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(54) Title: OBESITY TREATMENT TOOLS AND METHODS

(57) Abstract:

OBESITY TREATMENT TOOLS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Patent Application Serial No. 09/871,297 filed May 30, 2001 and to U.S. Patent Application entitled "Overtube Apparatus For Insertion Into A Body" filed May 23, 2002.

TECHNICAL FIELD OF THE INVENTION

[0002] The present invention relates generally to tools and methods for the treatment of obesity. More particularly, the present invention relates to tools and methods for performing less traumatic gastroplasty procedures.

BACKGROUND OF THE INVENTION

[0003] Obesity is considered a major health problem with annual associated costs reaching $100 billion in the U.S. alone. Morbid obesity is a condition of obesity with the presence of a secondary debilitating progressive disease and is generally associated with a body mass index (BMI) ≥ 40 kg/m^2. While the basic mechanism of obesity is simply an imbalance between caloric intake and burn rate, the underlying factors are varied and complex and conservative attempts at sustained weight loss with this population are almost always unsuccessful. Often, there are genetic and other biological influences that may override environmental causes. Consequently, obesity is a disease that eludes a simple treatment, with a recurrence rate above 90% for those who attempt to lose weight. Moreover, long-term results using conservative treatments for morbid obesity are generally unsuccessful and are typically associated with further loss of self-esteem with the regaining of weight. Hypertension, cardiovascular disease, diabetes, along with a host of other comorbidities all make morbid obesity second only to smoking as a preventable cause of death.

[0004] Surgical procedures for obesity date back to 1889 (Billroth) with the earliest peer reviewed procedure being the jejuno-ileal bypass in 1954 (Kreman). A successful procedure is commonly defined as one that results in at least 50% excess weight loss at 2 years. Today, the most commonly done operation is the Roux-en-Y gastric bypass (RYGB), with around 35,000

performed annually in the U.S. Other forms of bariatric surgery include Fobi pouch, bilio-pancreatic diversion, and gastroplasty or "stomach stapling". The single existing procedure that involves an implanted device is the Lap-Band, which is a laparoscopically installed inflatable cuff that is placed around the top of the stomach just below the lower esophageal sphincter (LES). This device affects satiety only (no reduced caloric absorption). Because there is more to obesity than simple overeating, it is unlikely that Lap-Band by itself will ever be as effective as a surgery that includes other physiologic feedback mechanisms.

[0005] The RYGB procedure is a procedure which has become very common in bariatric surgery. This procedure facilitates the movement of the jejunum to a high position by using a retrocolic Roux-en-Y loop. The procedure is generally performed through a 6-8 inch incision extending from the end of the breastbone to just above the navel. The stomach is completely divided into 2 unequal portions (a smaller upper and a larger lower gastric pouch) using an automatic stapling device with the raw surface reinforced with additional sutures. The upper pouch typically measures less than about 1 ounce or 20 cc, while the lower larger pouch remains generally intact and continues to secrete stomach juices flowing through the intestinal tract.

[0006] A segment of the small intestine (just distal of the duodenum or proximal of the jejunum) is then brought from the lower abdomen and joined with the upper pouch to form an end-to-end anastomosis created through a half-inch opening, also called the stoma. This segment of the small intestine is called the "Roux loop" and carries food from the upper pouch to the remainder of the intestines, where the food is digested. The remaining lower pouch and the attached segment of duodenum are then reconnected to form another anastomotic connection to the Roux loop at a location approximately 50-150 cm (1.6-4.9 ft) from the stoma, typically using a stapling instrument. It is at this connection that the digestive juices from the bypassed stomach, pancreas, and liver enter the jejunum or ileum to aid in the digesting of food. Due to the small size of the upper pouch, patients are forced to each at a slower rate and are satiated much more quickly, thereby reducing the caloric intake (typically between about 1000-1200 Calories).

[0007] Because the food enters the intestines directly, conditions known as the "dumping syndrome" are created when certain types of "junk foods" are

consumed (usually sweets and other simple carbohydrates). This creates unpleasant feelings of nausea, diarrhea, nervousness, and sweating, which in turn discourages patients from developing unhealthy eating patterns. With the RYGB procedure, a loss of at least 50% of excess body weight (EBW) is maintained in approximately 60% of patients at 5 years with a reduced complication rate than other procedures.

[0008] In creating the anastomoses in the RYGB procedure, several methods have previously been developed to maintain channel integrity. However, the conventional RYGB procedure requires a great deal of operative time and because of the degree of invasiveness, post-operative recovery time can be quite lengthy and painful.

[0009] Aside from the RYGB procedure, another gastrointestinal disease which relates to the stomach is gastroesophageal reflux disease (GERD). The lower esophageal sphincter is located in a distal portion of the esophagus adjacent to the junction between the esophagus and the stomach. When food is digested, a properly functioning lower esophageal sphincter would allow food to pass from the esophagus to the stomach while preventing reverse flow. However, GERD is a disorder where the esophageal sphincter allows the stomach contents, which includes gastric acid and bile, to flow back into the distal portion of the esophagus. Some complications associated with GERD include heartburn, pulmonary disorders, chest pain, esophageal ulcers, esophagitis, Barrett's esophagus, and esophageal carcinoma.

[0010] Common treatments for GERD include the administration of prescription acid blockers. But these drugs afford only short term relief; additionally, these drugs can be expensive and may have long-term side effects. Surgical procedures have included a procedure called the Nissen fundoplication, where a portion of the gastric fundus is wrapped around the esophagus. The wrapped fundus applies pressure to the esophagus to limit the reverse flow of the stomach contents. Effectively elongating the esophagus by fundoplication or by extending it via a staple line may be done to treat GERD. Conventional fundoplication procedures may be effective at treating GERD, but they also have disadvantages. For instance, many of these procedures require large incisions to be made in a patient. Laparoscopic procedures typically require several smaller incisions formed in the abdominal wall for the insertion of instruments into the

patient's body. However, such procedures can be expensive and they can increase the risks of post-operative hernias, accidental organ perforations, and other related drawbacks.

[0011] Examples related to the field of gastroplasty are described below.

[0012] U.S. Patent No. 5,549,621 to Bessler et al., which is incorporated herein by reference in its entirety, pertains to an apparatus and method for performing vertical banded gastroplasty without the use of staples. The described device uses at least two clamping bars to create a tubular-shaped pouch. However, the device is deployed laparoscopically onto the external surface of the stomach.

[0013] U.S. Patent No. 5,382,231 to Shlain, which is incorporated herein by reference in its entirety, describes a device for transesophageal stomach retraction by a device having vacuum ports utilized to draw the stomach over the device. However, this device is used for manipulating and retracting a patient's stomach from the inside during a variety of surgical procedures and is not a permanent procedure for creating an internal pouch within the stomach itself.

[0014] U.S. Patent No. 5,345,949 to Shlain, which is incorporated herein by reference in its entirety, relates to laparoscopic methods and tools for inserting a banding device to bring the walls of the stomach adjacent to one another between the proximal pouch and the distal region of the stomach. But there is no procedure for the creation of an internal pouch internally created from the stomach.

[0015] Examples related to the field of GERD treatment are described below.

[0016] U.S. Patent No. 6,159,146 to El Gazayerli, which is incorporated herein by reference in its entirety, relates to a device which is inserted transesophageally and engages the inside anterior wall of the fundus and secures it to the side of the esophagus.

[0017] U.S. Patent No. 6,113,609 to Adams, which is incorporated herein by reference in its entirety, pertains to a system which includes placement of a distal anchor through a hole formed in the wall of the esophagus and through a hole formed in the gastric wall, which are then fastened together.

[0018] U.S. Patent No. 5,571,116 to Bolanos et al., which is incorporated herein by reference in its entirety, pertains to an invagination device which approximates the lower esophagus and the fundus of the stomach.

[0019] However, all of these examples are limited to treatments for GERD which involves the attachment of the fundus, or upper portion of the stomach, to the esophagus.

SUMMARY OF THE INVENTION

[0020] Various tools and methods of treatment for obesity are described herein which are less traumatic and less invasive than procedures currently available. A variety of methods for the treatment of obesity, as well as other gastric-related diseases, e.g., gastroesophageal reflux disease (GERD), are disclosed. One method involves reducing the size of the stomach pouch to limit the caloric intake as well as to provide an earlier feeling of satiety. This may be done by creating a smaller gastric pouch within the stomach. This procedure optionally may be enhanced by performing a pyloroplasty prior to and/or in conjunction with the pouch size reduction, i.e., rendering the pyloric sphincter incompetent. This increases the rate of stomach emptying, allowing sugars and fats to pass directly into the bowel, thereby inducing dumping. Moreover, the food in the stomach may be made to also bypass a proximal portion of the bowel, i.e., a portion of the duodenum and jejunum, by creating a gastric anastomosis thereby creating a malabsorption of sugars and fats which are mostly absorbed in the bypassed portion of the duodenum and jejunum. Sugars and fats entering the bowel directly from the stomach rather than passing through the pylorus and proximal duodenum and jejunum may cause "dumping" syndrome and diarrhea. This in turn may create enforced behavioral modifications, thereby discouraging the patient from eating these types of high-caloric foods.

[0021] In forming a modified pouch, a marking device, such as a bougie, may be used at the beginning of the procedure, to create a dye marker "road map" on the interior surface of the stomach from the pylorus to the esophagus. This may enable visualization by, e.g., an endoscope, to give the physician a clear reference point for staple or fixation element placement. A distal balloon, which is preferably attached to an inflation tip at a distal end, may be inserted into the

pylorus to stabilize the bougie during the procedure and may be inflated from the proximal end of the tubing by the physician.

[0022] In reducing the stomach size, one variation involves grasping the interior walls of the stomach, preferably via an endoscope advanced trans-esophageally, and placing one to several individual fixation elements on opposing interior walls and then bringing those fixation elements together. The stomach pouch may be modified and/or created by a variety of other device variations utilizing other methods, e.g., stapling opposing sides of a stomach together to form two separate lumens from within the interior surface of the stomach. An endoscopic stapling device may be used to accomplish such a task. Such an endoscopic stapler preferably brings two regions of tissue into apposition and may then apply a fastening element, e.g., staples, clips, tags, screws, etc., into the two regions of tissue to affix them together.

[0023] In addition to endoscopically applied stapling and clip devices, rotating and rotatable probes may also be used to form a modified smaller lumen within a main lumen. Such probes generally may be inserted into a stomach endoscopically and may engage a portion of the interior lining of the stomach and may then be rotated to roll the engaged portion of the stomach wall around the probe itself to bring the wall in apposition with another portion of the stomach wall. Such rotating probes may be used to create a blind-ended pouch of stomach within the main stomach lumen, or as with the other devices, may be used to create a smaller pouch exiting into the pylorus. Once the roll of stomach wall is brought into apposition, a row or a plurality of fasteners, e.g., staples, blind staples, clips, tags, adhesives, screws, etc., may be used to maintain the stomach. Moreover, other variations may include gastric volume reduction devices as part of the present invention. Such volume reduction devices generally may be inserted into a stomach trans-esophageally through the use of, e.g., an endoscope. The reduction device may be used to draw or engage a portion of the interior lining of the stomach; the drawn or engaged portion may then be eventually removed, either actively or through natural processes, e.g., pressure necrosis.

[0024] To aid in the overall effect, a pyloroplasty procedure may also be performed to enhance treatment. The pyloroplasty may be performed prior to (preferable), in conjunction with, or following the gastric reduction procedure. A pyloroplasty procedure typically results in the pyloric sphincter being rendered

incompetent. Generally, a pyloroplasty device may be passed endoscopically through the esophagus, into the stomach, and preferably into position in or across the pylorus. Energy or a stimulus is then preferably applied to the pylorus to render it incompetent.

[0025] Moreover, an additional anastomosis gastric bypass procedure may also be performed to further enhance treatment. The anastomosis procedure may be performed preferably prior to, in conjunction with, or following the gastric reduction and pyloroplasty procedures (if performed at all). The procedure generally involves endoscopically or laparoscopically creating a side-to-side anastomosis preferably from within the stomach and bowel and within the digestive tract. This procedure may be similar to the Roux-en-Y gastric bypass procedure but with minimal trauma.

[0026] In using any one of the gastric reduction tools as described herein, the treatment of a hollow body organ may require multiple passes by the tools described above. Accordingly, to facilitate patient treatment, an overtube assembly may be used in conjunction with those tools. Accomplishing such treatments may require multiple passes through the esophagus by the tools used. An overtube assembly which is preferably comprised of an overtube member is disclosed which may be inserted into the hollow body organ, e.g., the stomach, through the esophagus of the patient.

[0027] The overtube may define a working lumen throughout which preferably extends from the proximal end to the distal end of the overtube. At the distal end, at least one window, and preferably two or more windows may be defined opposite of one another. The windows are preferably defined in the shape of slots near or at the distal end of the overtube. The lengths and widths of these slots are preferably long enough to approximate a desired length of a boundary or junction line within the stomach. The slots are preferably located in apposition to one another, but other variations may include offset windows separated by a dividing wall within the overtube lumen, as well as windows which are both offset and alternating located in apposition to adjacent windows. The entire length of the overtube, or at least a majority of the length, is preferably flexible enough to be inserted within the body and conform to the curvatures within the body. Alternatively, the portions of the overtube length may be made to have different regions of flexibility. The overtube may also have a bendable region having a

flexibility which enables it to be manipulated or bent into arbitrary shapes either actively by the physician or surgeon or passively by an endoscopic device inserted within the overtube.

[0028] A separate drive tube may be inserted within the overtube lumen and is preferably freely adjustable, i.e., longitudinally as well as rotationally within the overtube. The drive tube itself has a lumen defined within through which an endoscopic device may be inserted within to extend beyond the distal ends of both the overtube and the drive tube to examine and/or identify tissue regions of interest. A fastener is also preferably located within the lumen of the overtube and may be located distally of the drive tube. The proximal end of the fastener may be configured to engage the drive tube and may be formed into a variety of different shapes. For instance, the fastener may be in the form of a linear shape (e.g., in the form of a spear, harpoon, rivet, etc.), in a staple configuration, or in a spiral or helical shape. The shape of the fastener is generally determined, *inter alia*, by the desired approximated tissue configuration and the configuration of the overtube, as described in further detail below. It is also preferably configured to remain attached to the drive tube or to the inner wall of the overtube lumen until the fastener is deployed into the tissue region of interest. To deploy the fastener into the tissue, the drive tube with the fastener connected thereto may be advanced distally through the overtube lumen while rotating the drive tube via a proximally actuated torquing force. As the drive tube is rotated, the fastener is advanced into the tissue while fastening the tissue in a manner similar to a screw.

[0029] The overtube assembly may also comprise a fluid port which is in fluid communication with the working lumen of the overtube and which is also in fluid communication with a pump which may be used to provide negative pressure to create a vacuum within the overtube lumen; any number of ports may be used. Furthermore, the fluid port and any other fluid ports, if used, may also be fluidly connected to positive pressure pumps either in parallel or alternatively switched. Moreover, the same pump may be used to provide both negative and positive pressure.

[0030] In use, the overtube assembly may be inserted, e.g., orally, into a patient and advanced within the esophagus until the distal end is within the stomach. Once in the stomach, the distal end may be actively or passively

positioned by the physician or surgeon until the device has been desirably positioned. The pump, which is preferably in fluid communication with the overtube lumen, may then be activated to create a vacuum within the overtube to draw portions of the identified tissue within the windows. Once the tissue has been adhered and drawn into the windows, the fastener or fasteners may be advanced into the invaginated tissue to secure it. If the procedure requires additional fasteners, the overtube device may be maintained in position within the stomach while the drive tube may be withdrawn from the region to position additional fasteners. Alternatively, the drive tube may be withdrawn or maintained in position and the endoscopic device may be removed from the overtube lumen to allow for the insertion of other tools or devices through the overtube into the region.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] Fig. 1A shows an example of a modified stomach having a smaller pouch created from the interior surface lining.

[0032] Fig. 1B shows a partial superior view of the cross section from Fig. 1A.

[0033] Fig. 2 shows a variation on a marking device or bougie for marking the interior surface of a stomach.

[0034] Fig. 3A shows a variation on positioning a marking device inserted into a stomach.

[0035] Fig. 3B shows a cross section view from Fig. 3A of a deflated stomach around the marking device.

[0036] Fig. 3C shows the cross section view from Fig. 3B of an insufflated stomach with the resulting marks.

[0037] Fig. 4A shows a view of the interior of the lesser curvature of a stomach with anchors attached.

[0038] Fig. 4B shows a cross section view from Fig. 4A with the anchors attached.

[0039] Fig. 5A shows a side view of a crimping variation on a fastening device.

[0040] Figs. 5B and 5C show a superior and side view, respectively, of several interlocked crimping devices from Fig. 5A.

[0041] Fig. 6A shows an isometric view of a zip-tie or ratcheted variation on a fastening device.

[0042] Fig. 6B shows a superior view of the device of Fig. 6A attached to the stomach wall.

[0043] Fig. 6C shows a superior view of another double zip-tie variation on a fastening device.

[0044] Fig. 6D shows the stomach of Fig. 6B with the fasteners cinched.

[0045] Fig. 6E shows a superior view of another perpendicular zip-tie variation on a fastening device.

[0046] Figs. 7A and 7B show a superior view of an extendable double hook device attaching to a stomach wall.

[0047] Fig. 7C shows the device of Fig. 7A locked by a crimping variation.

[0048] Figs. 8A and 8B show a superior view of a modified stomach maintained by a fastening staple.

[0049] Figs. 9A and 9B show isometric views of a variation on an endoscopic stapling device.

[0050] Fig. 10 shows an isometric view of a variation on a box stapling device.

[0051] Fig. 11A shows an assembly view of another stapling device variation.

[0052] Fig. 11B shows a side view of the device of Fig. 11A.

[0053] Fig. 12A shows an isometric view of a crescent shaped variation of a stapling device.

[0054] Fig. 12B shows an end view of the device of Fig. 12A showing a staple deploying.

[0055] Fig. 12C shows an interior side view of the device of Fig. 12A with a translating wedge sequentially deploying staples.

[0056] Fig. 13 shows an interior view of a stomach with an example of stapling device placement.

[0057] Fig. 14 shows an interior view of a stomach with an example of a modified stapling device which may be used for the treatment of GERD.

[0058] Fig. 15A shows an assembly view of a variation on an approximating device.

[0059] Figs. 15B to 15D show the process of invaginating stomach interior lining and fastening using the device of Fig. 15A.

[0060] Figs. 15E shows the assembly view of another variation of the device of Fig. 15A wherein the clip may be replaced by a screw.

[0061] Figs. 15F to 15H show the process of invaginating stomach interior lining and fastening using the device of Fig. 15E.

[0062] Fig. 16A shows an example of a modified stomach created by a rotating device variation.

[0063] Fig. 16B shows a superior cross section view of the stomach of Fig. 16A where the modified lumen may be created by rotating the interior stomach lining upon itself.

[0064] Fig. 16C shows an alternate superior cross section view of the stomach of Fig. 16A where the modified lumen may be created by rotating apposed portions of the interior stomach lining upon itself.

[0065] Figs 17A and 17B show an isometric and cross section view, respectively, of a vacuum tube variation.

[0066] Figs. 18A and 18B show an isometric and cross section view, respectively, of a counter-rotating vacuum tube variation.

[0067] Figs. 19A and 19B show an isometric and cross section view, respectively, of a vacuum tube variation with attachment points.

[0068] Figs. 20A and 20B show an isometric and cross section view, respectively, of a split tube variation.

[0069] Fig. 21 shows an example of placement within a stomach of a rotatable device variation.

[0070] Figs. 22A and 22B show the possible creation of a rotated lumen using the device of Figs. 19A and 19B.

[0071] Figs. 23A to 23D show the possible creation of a rotated lumen using the device of Figs. 20A and 20B.

[0072] Fig. 24A shows an isometric view of a variation on a dual rotatable tube device.

[0073] Figs. 24B and 24C show an end view and cross section view, respectively, of the device of Fig. 24A.

[0074] Fig. 25A shows a variation on an endoscopic vacuum device in a stomach.

[0075] Figs. 25B and 25C show an end view of a variation on lumen creation from the interior surface of the stomach using the device of Fig. 25A.

[0076] Fig. 26 shows an isometric view of a variation on a gastric volume reduction device.

[0077] Figs. 27A to 27D show the device of Fig. 26 inserted into a stomach to draw or cinch up lining tissue to reduce a volume of the stomach.

[0078] Fig. 28 shows another variation on a gastric volume reduction device utilizing a grasping device and a ligating device.

[0079] Figs. 29A and 29B show an isometric view on a variation of a gastric volume reduction device utilizing tractive rollers to draw tissue up between them.

[0080] Fig. 29C shows another variation of the device of Figs. 29A and 29B with ratcheted rollers.

[0081] Fig. 30 shows an isometric view of a variation on a pyloroplasty device with an angioplasty balloon.

[0082] Fig. 31 shows an isometric view of another variation on a pyloroplasty device with extendable probes.

[0083] Figs. 32A and 32B show variations on sphincterotome arms for use in a pyloroplasty procedure.

[0084] Fig. 33 shows a stomach with a distal portion of the wall of the lesser curvature removed to show a possible use for the device of Fig. 31.

[0085] Fig. 34A shows an isometric view of another variation on a pyloroplasty device with a combination cutting and stapling notch.

[0086] Fig. 34B shows the device of Fig. 34A in a possible use in a stomach.

[0087] Fig. 35 shows a representative and normal gastro-intestinal system of a person.

[0088] Fig. 36 shows an example of a gastro-intestinal system modified by a preferable anastomosis procedure.

[0089] Fig. 37 shows an isometric view of a variation on an anastomosis deployment device.

[0090] Fig. 38 shows a cross section view of an anastomosis assembly mating a portion of the stomach with a portion of the intestinal tract.

[0091] Fig. 39 shows a cross section view of another anastomosis assembly mating two different portions of the intestinal tract.

[0092] Fig. 40A shows an isometric view of an overtube assembly having a bendable distal region.

[0093] Fig. 40B shows optional shaping mandrels which may be inserted through or along the overtube assembly.

[0094] Fig. 41 shows a detailed assembly view of a variation on the distal end of the overtube assembly showing a fastener and a drive tube positioned within the overtube.

[0095] Fig. 42A shows a detailed isometric view of the proximal assembly of the overtube.

[0096] Fig. 42B shows a cross-sectioned profile of the assembly of Fig. 42A.

[0097] Fig. 43 shows a schematic of one example of the overtube assembly in use within a patient.

[0098] Fig. 44 shows a cross-sectioned end view of the overtube in use within a stomach lumen.

[0099] Fig. 45 shows an isometric view of the overtube within a stomach with the stomach and overtube walls partially removed for clarity.

[0100] Figs. 46A and 46B show isometric and end views, respectively, of one variation of the overtube distal end.

[0101] Figs. 47A and 47B show isometric and end views, respectively, of another variation of the overtube distal end having offset windows.

[0102] Figs. 48A and 48B show isometric views of an overtube variation within a stomach prior to tissue fixation and after, respectively.

[0103] Figs. 49A and 49B show isometric views of another variation of the overtube distal end having alternating windows.

[0104] Figs. 50A and 50B show side views of the overtube of Figs. 49A and 49B.

[0105] Fig. 51 shows a cross-sectioned side view of the overtube of Figs. 49A and 49B.

DETAILED DESCRIPTION OF THE INVENTION

[0106] With obesity becoming an increasing problem, various tools and methods of treatment are described herein which are less traumatic and less invasive than procedures currently available. As described in further detail below, a variety of methods for the treatment of obesity, as well as other gastric-related diseases, are disclosed. Generally, the size of the stomach pouch may be reduced to limit the caloric intake as well as to provide an earlier feeling of satiety. This may be accomplished by creating a smaller gastric pouch within the stomach by a variety of methods. This procedure optionally may be enhanced by performing a pyloroplasty prior to and/or in conjunction with the pouch size reduction, i.e., rendering the pyloric sphincter incompetent. Additionally, the food in the stomach may be made to also bypass a proximal portion of the bowel, i.e., a portion of the duodenum and jejunum, by creating a gastric anastomosis thereby creating a malabsorption of sugars and fats which are mostly absorbed in the bypassed portion of the duodenum and jejunum. Sugars and fats entering the bowel directly from the stomach rather than passing through the pylorus and proximal duodenum and jejunum may cause "dumping" syndrome and diarrhea. Moreover, rendering the pylorus incompetent may also lead to dumping syndrome partly because of the rapid gastric emptying which may occur. This in turn may create enforced behavioral modifications, thereby discouraging the patient from eating these types of high-caloric foods.

[0107] Fig. 1A shows an example of a modified stomach **10** which may be created, by any one of the methods described below, as part of the present invention. Greater curvature **12** and lesser curvature **14** is seen in modified stomach **10**, as well as the distal end of esophagus **16** and pylorus **18**. As part of the present invention, stomach **10** may be divided along junction **24** into modified pouch **22**, which is preferably less than about 1 ounce in volume, and main pouch **20**. Fig. 1B shows a partial superior view of the cross section of main pouch **20** and modified pouch **22** as viewed from cutting plane **P** from Fig. 1A. As seen, modified lumen **26** is preferably formed by junction **24** from main lumen **28** by joining a portion of stomach wall **30**. During ingestion of food, modified pouch **22** accepts food from esophagus **16** and preferably passes it directly through modified lumen **26** into pylorus **18**. Main pouch **20** may remain intact and function normally, but preferably sees little or no food. Acids and other fluids

that may be generated in main lumen 28 may drain through the reduced outlet near pylorus 18 and may pass through the digestive system normally.

Marking Tools and Methods

[0108] As part of forming a modified pouch, a marking device may be used, preferably at the beginning of the procedure, to create a dye marker "road map" on the interior surface of the stomach from the pylorus to the esophagus. Once such dye marks are placed, they may be visualized, e.g., endoscopically, thereby giving the physician a clear reference point for staple or fixation element placement. An example of such a marking device is shown in Fig. 2 as marking device or bougie 40. Bougie 40 is preferably an elongated device made from tubing member 44 which may have several channels defined within. Tubing 44 may be made from any variety of biocompatible materials, e.g., stainless steel, plastics, etc., and preferably has a diameter and cross section which is similar to that of the finished modified lesser pouch. Along the length may be defined a series of dye ports 46 through which the marking dye may be channeled through from the proximal end of bougie 40. Any variety of biocompatible dyes which preferably enhance visualization may be used, e.g., methylene blue, thionine, acridine orange, acridine yellow, acriflavine, quinacrine and its derivatives, brilliant green, gentian violet, crystal violet, triphenyl methane, bis naphthalene, trypan blue, and trypan red. Also along the length and on either side of dye ports 46 may be a series of vacuum ports 48, which are optional. A distal balloon 52, which may be inserted into the pylorus to stabilize bougie 40 during the procedure, is preferably attached to inflation tip 50 at distal end 42 and may be inflated from the proximal end of tubing 44 by the physician.

[0109] Figs. 3A to 3C show bougie 40 during one method of use. Fig. 3A shows stomach 60 as bougie 40 is inserted down through esophagus 62. As bougie 40 is advanced down to pylorus 76, distal balloon 52 may be inflated through inflation tip 50, thus securing the device. Bougie 40 preferably follows lesser curvature 64 and may alternatively be shaped to approximate lesser curvature 64. Bougie 40 is also preferably rotated such that dye ports 46 face away from lesser curvature 64 and face towards greater curvature 66. Then the air and fluids contained within stomach 60 are preferably removed, either through vacuum ports 48, if they are included in bougie 40, or through another vacuum

port which may be introduced endoscopically through esophagus 62. Fig. 3B shows cross section 3B-3B from Fig. 3A as deflated stomach 60. Once deflated, modified lumen 70 may take shape around bougie 40, separate from deflated main lumen 68. In this deflated state, the dye may be channeled through dye ports 46, thereby leaving dye marks 72 on interior lining 74. Once the staining has been performed, lumen 68 may be insufflated, as shown in Fig. 3C, and bougie 40 may then be removed. As seen in Fig. 3C, dye marks 72 mark or delineate the junction region where anchors or fasteners may be placed to draw interior lining 74 together to form the modified lumen.

Gastric Reduction Tools and Methods Using Fasteners

[0110] One variation of reducing the stomach size involves grasping the interior walls of the stomach, preferably via an endoscope advanced trans-esophageally, and placing one to several fixation elements on opposing interior walls and then bringing those fixation elements together.

[0111] Several examples of different possible variations on fasteners are shown and described below. These variations are not intended to be limiting but are merely given as illustrative examples.

[0112] Fig. 4A shows a view of the interior of the lesser curvature of stomach 60 with part of the greater curvature wall removed. As seen, individual anchors 80 may be secured to the interior surface along the junction 24 where modified pouch 22 from Fig. 1A would form. Anchors 80 may be of any biocompatible material, e.g., stainless steel, polymers, etc., which may be formed into a variety of fasteners, e.g., staples, ratcheted wires, zip ties, clips, tags, eyelets, crimps, and screws. Anchors 80 may be placed by estimating the junction boundary, but they are preferably located along dye mark 72, which may be formed by methods and tools described above, prior to anchor 80 placement, as shown in Fig. 4B, which is cross section 4B-4B from Fig. 4A. After anchors 80 have been fastened, suture 82 may be drawn through each of the anchors 80, preferably in a zig-zag manner, and then suture 82 may be drawn tight to bring the opposing surfaces of interior lining 74 together in apposition along dye marks 72 to form the modified lumen. Alternatively, individual anchors 80 may be preloaded or prefastened by suture 82, and anchors 80 may be fastened to interior lining 74 in this manner.

[0113] Fig. 5A shows a side view of a variation on a fastening device in crimping member **90**. Crimping member **90** is preferably made from a biocompatible material, e.g., stainless steel, nitinol, etc., and may be formed to have elbow **92** extend into two opposing anchoring ends **94**. Fig. 5B shows a superior view of a created modified lumen **100** formed from main lumen **98** by any of the methods described herein. In this variation, several crimping members **90** may be attached or fastened to interior lining **96** by anchoring ends **94**. As they become attached, each of the members **90** are preferably configured to interlock with an adjacent crimping member **90**, much like a zipper. Fig. 5B shows the interlocked members **90** from the top to form lumen **100** and Fig. 5C shows the view from 5C-5C from Fig. 5B where each of the crimping members **90** are shown interlocking at their elbows **92** like a zipper.

[0114] Fig. 6A shows an isometric view of another variation on a fastening device in ratcheted wire or zip tie **110**. This particular variation shows a distal tip or male end **112** and a corresponding proximal end or female end **114**, with ratcheted length **116** between those two ends. Fig. 6B shows a superior view of stomach wall **120** just prior to the formation of modified lumen **124** from main lumen **122**. As seen, male end **112** of first zip tie **110'** may be pierced through one side of interior lining **118** and second zip tie **110''** may be pierced through the opposing side of interior lining **118** such that the male ends **112** of each zip tie preferably correspond to the female ends **114** of the other zip tie. To then form the lumen **124**, each zip tie **110'**, **110''** may be drawn together and tightened accordingly, as shown in Fig. 6D. A plurality of zip ties **110** are preferably used to form modified lumen **124** by aligning them by any of the methods described above.

[0115] An alternative zip tie device which may be used is a perpendicular type version of zip tie **110**. As shown in Fig. 6E, first perpendicular zip tie **134'** and second perpendicular zip tie **134''** may be used in place of zip tie **110** and lumen **124** may be formed in much the same manner as described above to result in the modified stomach as shown in Fig. 6E. A further alternative is shown in Fig. 6C where male zip tie **126** preferably has dual piercing male ends with catcher tubes **128**. In this variation, a vacuum-type device, as described below in detail, or forceps may be used to draw portions of stomach wall **120** in apposition. As the apposed stomach walls **120** are positioned, needles **130**, which are

preferably passed through a double female zip tip **132**, may be used to pierce through tissue **120** and lock into catcher tubes **128**. Needles **130** may then be drawn back through tissue **120**, while simultaneously pulling male ends/catcher tubes **128** back through tissue **120** and into the corresponding double female zip tie **132**. The locked zip tie **126** may then be drawn tight against female zip tie **132**, trimmed, and then released. This procedure may be repeated for any number of zip ties which may be used to draw the stomach lining together to form the smaller pouch and may also be used with the dye marking device **40** and procedure as described above.

[0116] A further variation on the individual anchoring fasteners is shown in Fig. 7A. This variation shows gasping device **140** with retaining tube **142** and extendable members **146** which may extend from distal opening **144**. Extendable members **146** are preferably made from a biocompatible material, e.g., superelastic or shape memory alloy such as nitinol, which may be biased to urge away from a longitudinal axis defined by tube **142** once extended beyond distal opening **144**. As members **146** extend, they may reach out to grasp apposed portions of interior lining **150** by hooks **148**. As above, the locations where hooks **148** grasp may be defined by the marking device as described above and viewed by the physician through, e.g., an endoscope. Once hooks **148** have grasped the appropriate portion of lining **150**, members **146** may then be drawn back through distal opening **144**, as shown in Fig. 7B, and a retaining device, such as crimp **152**, may be slid over a distal section of members **146**, as shown in Fig. 7C, to maintain the position of hooks **148** and apposed lining **150** to create the desired lumen.

Gastric Reduction Tools and Methods Using Stapling Devices

[0117] Aside from individual anchoring and fastening devices, the stomach pouch may be modified and/or created by a variety of other device variations utilizing other methods. Fig. 8A shows the cross sectioned superior view of Fig. 1B with the addition of staple **160** maintaining junction **24**. The figure shows an example of how, e.g., an endoscopically applied stapler, may be used to retain and hold junction **24** to form modified lumen **26**. Fig. 8B shows a close-up view of the junction **24** and staple **160** which was applied from within lumen **26**.

[0118] To staple opposing sides of a stomach together to form two separate lumens from within the interior surface of the stomach, an endoscopic stapling device may be used to accomplish such a task. Such an endoscopic stapler preferably brings two regions of tissue into apposition and may then apply a fastening element, e.g., staples, clips, tags, etc., into the two regions of tissue to affix them together. These stapling devices may optionally incorporate the use of the marking device or bougie **40**, as described above, as a preliminary step as a guide to vacuum placement and/or stapling to form the desired modified lumen. The fastening elements, e.g., staples, are preferably made of a biocompatible material such as stainless steel, titanium, polymers, sutures, nitinol, or any other similar metals and alloys, etc. and may be in any conventional shape such as C-shaped and U-shaped staples or any of the other shapes as described herein. The two regions of tissue may be adhered to the stapling device by a variety of attachment methods, e.g., tines, barbs, hooks, vacuum, or any combinations thereof. In an adhering device utilizing a vacuum to hold the apposing regions of tissue together, such a device may be a tubular or wand-shaped member and preferably has at least two windows which may be spaced about the circumference of the tube or wand. These windows may be separated by an arc in a range of about 20° to 180° about the longitudinal axis defined by the length of the tube or wand, and are preferably separated by an arc in a range of about 90° to 180°.

[0119] Several examples of different possible variations on the stapling device are shown and described below. These variations are not intended to be limiting but are merely given as illustrative examples.

[0120] Fig. 9A shows a variation of an endoscopic stapling device in the isometric view of anvil stapling device **170**. Stapling unit **172** is shown attached to the distal end of tube **174**. Within stapling unit **172** is staple enclosure **176** where staples may be loaded and vacuum ports **178** which are seen in an alternating fashion with staple slots **180**, through which the staples may be deployed. Fig. 9B shows a reverse isometric view of the device of Fig. 9A. As seen, stapling unit **172** may have septum **184** insertable into septum slot **186**, which is preferably midway between the sides of staple enclosure **176** and which may separate the interior of staple enclosure **176** into two separate chambers. Septum **184** may serve several functions, one of which may be to allow selective

activation of opposing sides of vacuum ports **178** of unit **172** as tissue is selectively adhered to the device. Other functions of septum **184** are discussed below.

[0121] In operation, stapling unit **172** may be inserted trans-esophageally into a stomach and a first portion of the interior lining may be adhered to a single side of staple enclosure **176** through a vacuum created within vacuum ports **178**. The vacuum may be created in stapling unit **172** through tube **174** and activated from the proximal end of tube **174** from outside the patient's body. Once the first portion of the interior lining is adhered to one side of staple enclosure **176**, the opposite set of vacuum ports **178** may be activated and unit **172** may be used to draw the first portion to an opposing second portion of the interior lining, which may then be adhered to the device such that the first portion and the second portion are preferably in apposition to each other. This action preferably forms the modified lumen **26** of Figs. 8A and 8B. As the tissue is held to unit **172**, septum **184** may be withdrawn from septum slot **186** by introduced forceps through, e.g., an endoscopic or through an integral actuator, to form a single chamber within staple enclosure **176**. Removal of septum **184** may then bring the first and second portions of tissue into contact apposition. The side surfaces **188** of septum **184** may incorporate a cutting, abrading, scoring, heating, freezing, chemically damaging, or some other damaging surface to tissue. Such a surface **188** may damage the interior lining contacting each other upon removal of septum **184** as surface **188** slides past. This damage may encourage a more vigorous healing response and a more permanent fixation between the damaged tissue once stapled or affixed together.

[0122] After removal of septum **184**, the staples loaded within staple enclosure **176** may be fired through staple slots **180** to affix the tissue. As the staples are fired, anvil **182** may be used as an anvil to secure the staples to the tissue, thereby resulting in the modified lumen **26** as shown in Fig. 8B. The length of stapling device **170** may be made according to the desired junction length and the size of the patient's stomach. This particular variation may be withdrawn from the area after the stapling procedure by first pushing the stapling device **170** past the resulting staple line.

[0123] Fig. 10 shows an isometric view of another variation in box stapling device **190**. Stapling unit **192** is shown as being attached in fluid

communication to vacuum tube **193**. Stapling device **190** may be inserted and operated in the same manner as device **170** described above. Stapling unit **192** may have vacuum ports **194** activated selectively on either side of septum **196** as described above. The tips of staples **198** are shown partially deployed for illustration purposes, but are preferably not deployed until septum **196** is first retracted preferably in the direction as indicated. Septum **196** may also be configured to damage the contacting tissue upon septum **196** withdrawal in the same manner as described above. Stapling device **190** may be easily applied and removed after staples **198** have been deployed.

[0124] Fig. 11A shows an assembly isometric view of another variation in stapling device **200**. This variation **200** shows curved tube **202** which may have lumen **204** house staples **206** as well as act as a combination vacuum and staple slot **216**. Tube **202** may be shaped in a variety of ways but is shown here as a C-shaped or U-shaped tube with first channel **210'** and second channel **210''**, for adhering the two apposed portions of tissue, preferably separated by removable septum **212**. With this variation **200**, tissue may be adhered within the channels **210'**, **210''** through vacuum/staple slot **216** and once positioned, staples **206** may be deployed while septum **212** is removed simultaneously by the use of curved wedge **218**. In operation, curved wedge **218** may be drawn within lumen **204** from the tube **202** distal end to the proximal end by, e.g., a pull-wire attached to wedge **218**. As wedge **218** is advanced proximally, wedge **218** would preferably force pivot **208** of staple **206** against contact edge **214** of septum **212**. As wedge **218** is advanced further proximally, urging end **220** may then urge the curved ends of staple **206** to rotate about pivot **208** and deploy through slot **216**. While staple **206** is deploying, notch **222**, preferably located at a distal end of wedge **218**, may engage contact edge **214** and begin to slide septum **212** simultaneously towards the proximal end of tube **202**. Fig. 11B shows a side view of stapling device **200** of Fig. 11A. As seen, curved wedge **218** preferably contacts septum **212** via notch **222** and pushes while simultaneously urging staple **206** to deploy. The figures show a single staple **206** for illustrative purposes only and any plurality of staples **206** may be used in practice depending upon the desired results.

[0125] Fig. 12A shows an isometric view of yet another variation in stapling device **230**. This variation may omit a removable septum. Curved tube

232 is preferably curved in this variation in a crescent shape forming contact channel 234. Within contact channel 234, a number of vacuum ports 236 and staple slots 238 may be defined in an alternating pattern, as shown. A possible W-shaped staple 240 preferably having pivot 242 at the staple 240 midpoint is shown outside of tube 232 for illustrative purposes in a possible orientation for insertion within staple slots 238. Fig. 12B shows cross section 12B-12B from Fig. 12A. As seen, tube 232 defines lumen 244, which preferably runs the length of tube 232, and translating wedge 246 which is preferably slidingly disposed within lumen 244. As seen in Figs. 12B and 12C, which is a side view of the interior of tube 232, wedge 246 may be translated by pull-wire 248. Pull-wire 248, which may be made of any high-strength material, e.g., stainless steel, nitinol, nylon, polymers, etc., may be manipulated by a physician from the proximal end of tube 232 from outside of the patient's body. Like the device 200 of Figs. 11A and 11B, once vacuum ports 236 have acquired the interior tissue lining to be approximated, translating wedge 246 may be advanced proximally. Advancing wedge 246 may urge staples 240 to deploy through staple slots 238 sequentially as shown to hold the tissue and form the desired lumen.

[0126] An example of deployment for any of the stapling devices described above is shown in Fig. 13. As shown, stomach 250 with the wall partially cut out is seen with stapling device 252 inserted within. Stapling device 252 is shown merely as an example of insertion and could comprise any of the devices described herein. Device 252, which is preferably advanced trans-orally into stomach 250 and through esophagus 256, is preferably located at the distal end of delivery/vacuum tube 254. Once inserted, device 252 may be located by the assistance of the lesser curvature 258 of stomach 250. Also shown are vacuum/staple ports 260, which may be any of the configurations as described herein. In a preferable variation, stapling device 252 may be configured to produce a staple line or junction following the lesser curvature beginning from cardiac notch 264 down towards pylorus 262. Accordingly, device 252 may have the length and vacuum/staple ports 260 configured such that the distal end of device 252 points towards pylorus 262.

[0127] Fig. 14 shows stapling device 270 in a slightly different configuration for the treatment of other gastro-intestinal diseases such as gastroesophageal reflux disease (GERD), as discussed above. The stomach 250

of Fig. 13 is shown, but for the treatment of GERD, stapling device **270** may be slightly modified such that the device **270** and vacuum/staple ports **272** may be straight or flared away from, rather than towards, lesser curvature **258** and pylorus **262** as described above. As such, vacuum/staple ports **272** would preferably produce a staple line or junction beginning from cardiac notch **264** and then flares away from lesser curvature **258** and pylorus **262**. Device **270** may be any of the devices described and operated herein, but for the flared modification. Likewise, any of the devices described herein may be used for the treatment of GERD by simply angling the device to produce a flared staple line. Alternatively, a simple non-flared staple line may also suffice for treating GERD. The staple line may act as a Heimlich valve which preferably closes down in response to pressure exerted from the greater or main lumen. Moreover, the smaller volume of the modified lumen in-line with esophagus **256** may provide a smaller volume of acid available for esophageal reflux.

[0128] An isometric view of a single channel vacuum device variation is shown in Fig. 15A in approximating device **280**. Tube **282** is preferably a tubular device which may be inserted into a stomach through the esophagus of a patient. A lumen **284** may run through tube **282** from a proximal end to the distal end of tube **282**. At the distal end, two or more windows or slots **286** are preferably defined opposite of one another, as shown. The lengths and widths of slots **286** may vary and is preferably long enough to approximate the desired length of the boundary or junction line of the modified lumen; likewise, the width is preferably wide enough to accommodate at least two layers of the stomach interior lining. Approximating clip **288** is shown having at least two piercing ends **290** and may be loaded into tube lumen **284** from either the proximal end or distal end of tube **282** preferably prior to inserting the device **280** into the patient. Clip **288** is preferably made of a biocompatible material as described above. Biodegradable plug **292** may be placed into the distal end of tube **282** prior to insertion into the patient and is preferably made of a biocompatible biodegradable material, e.g., biodegradable polymers such as polylactide, polyglycolide, and their copolymers. Plug **292** may be alternatively made from a non-biodegradable material and may simply pass after the procedure. Plug **292** may aid in maintaining a vacuum seal through slots **286** during the approximation procedure, as described below.

[0129] Fig. 15B shows an end view from section 15B-15B from Fig. 15A of tube 282 in operation. As shown, opposing portions of stomach interior lining 294 may be drawn into lumen 284 through opposing slots 286 by creating a vacuum within lumen 284. Approximating clip 288 may be urged distally through tube 282 such that each of ends 290 may be drawn through a corresponding slot 286 over and/or pierced through lining 294 within lumen 284. As lining 294 is approximated within lumen 284, biodegradable plug 292 may become invaginated within lining 294. Accordingly, as clip 288 and ends 290 are positioned over lining 294, tube 282 may be withdrawn from the area while clip 288 preferably slides through the distal end of tube 282 leaving the approximated interior lining 294 held in position by ends 290, as seen in Fig. 15D. Removal of tube 282 may urge plug 292 to slide off the distal end of tube 282 and remain within the newly formed lumen to become degraded over time or to pass through the patient's system.

[0130] Fig. 15E shows the device of Fig. 15A, but in this variation, clip 288 may be replaced by screw 289, which is preferably in the shape of a helix or coil having a tapering width or diameter. The first few turns or coils of screw 289 may have the same or similar diameter than the remaining tapering coils; this may enable piercing end 291 to engage interior 294 and may also allow screw 289 to be advanced at the desired orientation through the tissue. Screw 289 preferably maintains a parallel orientation with tube 282 during delivery into the tissue, i.e., a longitudinal axis defined by screw 289 is preferably parallel, or close to parallel, with the longitudinal axis defined by tube 282. Moreover, the outer diameter of the first few turns or coils are preferably the same diameter, or slightly less than, the inner diameter of tube 282. This may further enable screw 289 to be advanced through lumen 284 at the proper orientation prior to engaging interior 294.

[0131] As described above for the device of Figs. 15A to 15D, opposing portions of stomach interior lining 294 may be drawn into lumen 284 through opposing slots 286 by creating a vacuum within lumen 284, as shown in Fig. 15F. Screw 289 may then be urged through lumen 284 and rotated in the direction of the arrow shown until piercing end 291 engages the invaginated lining 294. Piercing end 291 preferably is sharp and needle-like to enable piercing through multiple layers of lining 294. As screw 289 is further rotated, it may be further advanced distally through the remaining portion of invaginated lining 294. The

tapering diameter and decreasing width may also begin to further approximate the opposing edges of lining **294** towards one another, as shown in Fig. 15G. Finally, as seen in Fig. 15H, further advancement of screw **289** preferably draws the opposing surfaces into contact with one another. Tube **282** may then be removed, as described above. Although the fixation of one screw **289** is described, multiple screws **289** may be fastened one after another to form a continuous fixation line.

[0132] Screw **289** may be made of a bioabsorbable or biocompatible material, as described herein such as a polymer or superelastic alloy, and may be integrally formed with barbs or whisker-like filaments protruding along its length to help prevent screw **289** from backing out once it has been engaged within the lining **294**. An example of a spiraling suturing needle or screw which may be used in this variation is shown and described in U.S. Patent No. 5,330,503 to Yoon, which is incorporated herein by reference in its entirety. Another example of a helical fastener or screw and applicator which may be used in this or another variation is shown and described in U.S. Patent No. 5,582,616 to Bolduc *et al.*, which is also incorporated herein by reference in its entirety. Other examples of helical fasteners or screws and applicators are also shown in U.S. Patent No. 5,810,882; U.S. Patent No. 5,824,008; and U.S. Patent No. 5,964,772; all to Bolduc *et al.*, each of which is incorporated herein by reference in their entirety.

Gastric Reduction Tools and Methods Using Rotatable Devices

[0133] Aside from endoscopically applied stapling and clip devices, rotating and rotatable probes may also be used to form a modified smaller lumen within a main lumen. Such probes generally may be inserted into a stomach endoscopically and may engage a portion of the interior lining of the stomach and may then be rotated to roll the engaged portion of the stomach wall around the probe itself to bring the wall in apposition with another portion of the stomach wall. Such rotating probes may be used to create a blind-ended pouch of stomach within the main stomach lumen, or as with the other devices, may be used to create a smaller pouch exiting into the pylorus. Once the roll of stomach wall is brought into apposition, a row or a plurality of fasteners, e.g., staples, blind staples, clips, tags, adhesives, etc., may be used to maintain the stomach. The tubes themselves may be made of any variety of biocompatible materials which

preferably have sufficient strength to undergo a torsional load, e.g., stainless steel, nickel, platinum, etc.

[0134] An example of a stomach modified by such a rotating probe or device is shown in Fig. 16A. Main pouch **300** is seen with modified pouch **302** formed along the lesser curvature of the stomach and delineated by junction **304**. This example shows modified pouch **302** extending from esophagus **306** and terminating in pouch opening **308** proximally of pylorus **310**. Pouch opening **308** may also be made to terminate at pylorus **310**.

[0135] Fig. 16B shows a superior view from cross section 16B-16B from Fig. 16A of one variation on producing modified pouch **302** having modified lumen **314** from main pouch **300** having main lumen **312** where junction **304** may be formed by rotating the stomach upon itself. Fig. 16C shows an alternative superior view from cross section 16B-16B from Fig. 16A where modified pouch **302'** having modified lumen **314'** may be formed from main pouch **300'** having main lumen **312'**. In this particular variation, junction **304'** may be formed by taking apposed sides of the interior stomach lining near the lesser curvature and approximating them to form modified lumen **314'**.

[0136] Several examples of different possible variations on the rotating probe or device are shown and described below. These variations are not intended to be limiting but are merely given as illustrative examples.

[0137] Fig. 17A shows vacuum tube **320** which may have an elongate tubular body. Tube **320** may be inserted into a patient's stomach trans-esophageally via, e.g., an endoscope. Accordingly, distal end **322** is preferably rounded or gently tapered to be atraumatic to the patient. An opening or window **324** may be defined in the wall of tube **320** near distal end **322** and as seen in Fig. 17B, opening **324** is preferably in communication with lumen **326**, which may run throughout tube **320**. The geometry of opening **324** is preferably large enough to accommodate the invagination of tissue from the interior stomach lining by a vacuum created within lumen **326** and opening **324**. The vacuum may be activated by the physician from a proximal end of tube **320** from outside of the patient. Once tissue is invaginated within window **324**, a fastening member may be inserted and deployed to secure the interior stomach lining thereby reducing its overall volume, as described in further detail below. As shown in Fig. 17B, which is cross section 17B-17B from Fig. 17A, tube **320** preferably has a diameter and

cross section which may approximate a final geometry of the newly created lumen within the stomach.

[0138] Fig. 18A shows an isometric view of another variation in counter-rotating tube 330. Counter-rotating tube 330 may have a gently tapered distal end 332 with an opening 334 defined in the tube wall near distal end 332. Preferably contained within tube 330 is an additional inner tube 336, which may be geometrically similar to tube 330 but with a diameter small enough to allow free rotation about the longitudinal axis preferably shared by both tubes 330 and 336. Inner tube 336 likewise may have inner opening 338, which may allow communication between lumen 340 and openings 334 and 338. As above, a vacuum may be activated from a proximal end of tube 330 to draw tissue from the interior stomach lining through lumen 340 and into openings 334 and 338 when they are aligned. As shown in Fig. 18B, which is cross section 18B-18B from Fig. 18A, once the tissue has become invaginated within openings 334, 338, inner tube 336 may be rotated to effectively pinch and firmly hold the tissue in place, as shown in Fig. 18B. The addition of the pinching action in addition to the vacuum may aid in holding the tissue, thereby aiding in the rotation of both tube 330 and inner tube 336 when forming the modified lumen. Both tubes 330 and 336 may be manipulated and rotated from a proximal end of the tubes from outside of the patient.

[0139] Fig. 19A shows an isometric view of another variation in barbed tube 350. Tube 350 may be similar to vacuum tube 320 described above. Distal end 352 is preferably tapered and opening 354 may be defined in the wall of tube 350 near distal end 352. Additionally, at least one and preferably several attachment points 356, e.g., tines, barbs, or hooks, may be defined along at least a single edge around opening 354. Attachment points 356 are preferably defined along the leading edge of opening 354 for rotation of tube 350. Fig. 19B, which is cross section 19B-19B from Fig. 19A, shows opening 354 preferably in communication with lumen 358 and a preferred orientation of attachment point 356.

[0140] Fig. 20A shows an isometric view of yet another variation in split tube 360. Split tube 360 may be formed of at least two splittable halves, e.g., first half 364 and second half 366, which may be joined together longitudinally along split 370. When first half 364 and second half 366 are joined together, split tube

360 preferably forms a tapered distal end 362. Split tube 360 may also define a lumen 372 which may run throughout the length of split tube 360. This variation may also comprise at least one and preferably several attachment points 368 on each of first half 364 and second half 366. As shown in the figure, first half 364 may have a row of attachment points 368 preferably aligned along a portion of split 370 and second half 366 may likewise have a row of attachment points 368 juxtaposed and preferably mirroring those located on first half 364. Attachment points 368 may be of any type described above and the number and positioning of attachment points 368 may depend upon the desired length of the resulting junction formed upon rolling the stomach. Fig. 20B, which is cross section 20B-20B from Fig. 20A, shows split 370 and an example of the juxtaposed relationship of attachment points 368.

[0141] Fig. 21 shows an example of a rotatable probe device during insertion into stomach 380. As seen, tube 384 may be inserted into stomach 380 via esophagus 382, preferably endoscopically. Tube 384 may be any of the devices described above and is shown generally as an example of how such devices may be inserted into an organ, e.g., stomach 380. As tube 384 is inserted, it may engage a portion of the interior of stomach 380, preferably along lesser curvature 386. The engagement may be accomplished by any of the methods described herein, e.g., attachment points partially piercing the stomach lining, a vacuum adhering a portion of the lining, etc. Once engaged, tube 384 may then be rotated to roll the engaged portion of the stomach wall around the probe itself to bring the wall in apposition with another portion of the stomach wall.

[0142] Fig. 22A shows a variation on partial cross section 22/23-22/23 from Fig. 21 with tube 350 from Figs. 19A and 19B in a preferred operation. As shown, interior lining 390 may be adhered to tube 350 via a vacuum created in opening 354 through lumen 358 and/or via attachment points 356 which may partially pierce lining 390, as described above. The location for adhering tube 350 may also be determined or aided by the use of marking device 40, as described above. Once the desired location of interior lining 390 has been established, tube 350 may be rotated about its longitudinal axis, following the arrow as shown, by at least about 180° and preferably at least about 360°. Lining 390 is preferably rotated until the adhered portion contacts a second portion of lining 390 to result in the modified lumen 314 of Fig. 22B, also shown in Fig.

16B. Once modified lumen **314** has been formed, fasteners may be fired or deployed through opening **354** or via a separate endoscopic stapling device at location **392** to secure and maintain modified lumen **314**. Fasteners may comprise any of the fasteners as described herein, e.g., staples. Once modified lumen **314** has been secured, tube **350** may then be removed. Fig. 16B shows newly created modified pouch **302** with modified lumen **314** and, as seen, interior lining **390** also forms the interior surface defining modified lumen **314**.

[0143] Figs. 23A to 23D show another variation on partial cross section 22/23-22/23 from Fig. 21 with split tube **360** from Figs. 20A and 20B. Split tube **360** may be inserted into the stomach either as separate halves **364, 366** individually or as a whole tube which may then be split while in the stomach. Once separated, first half **364** and second half **366** may be engaged to interior lining **390** by attachment points **368** at a slight distance from one another. The separation distance may be determined by the desired resulting size of the lumen. Alternatively, the separation distance may be determined or aided by the use of marking device **40**, as described above.

[0144] Once first half **364** and second half **366** have engaged interior lining **390**, as shown in Fig. 23A, each of free ends **394** of halves **364, 366** may then be rotated in the direction of the arrow, as shown. Free ends **394** may be configured to simply contact each other or to interlock with each other and rotate about a hinge or pivot. As first half **364** and second half **366** continue to be rotated, Figs. 23B and 23C show the progression of lumen formation as attachment points **368** draw around and towards one another. Finally in Fig. 23D, as split tube **360** is preferably formed again, modified lumen **314'** may be formed, as also shown in Fig. 16C, to then be secured or maintained preferably by fasteners, e.g., staples, which may be deployed through junction **304'**.

[0145] A further variation on a rotating device is shown in the isometric view of dual tube device **400** shown in Fig. 24A. Dual tube device **400** may have at least two elongate members, first member **402** and second member **404**, which may be rotatingly attached to controlling device **406** and may be parallel to each other. The members **402, 404** are preferably counter-rotating and may be rotated by a rotation control **408**, which is preferably located on controlling device **406**. First member **402** may have first distal end **410** offset slightly from the longitudinal axis of first member **402** by first bend **412**. First opening **414** is also

preferably defined in the wall of first member 402 proximally of first distal end 410. Second member 404 is preferably similar to first member 402 and may have second distal end 416 offset slightly from the longitudinal axis of second member 404 by second bend 418. Near second distal end 416, second opening 420 may be defined in the wall of second member 404.

[0146] Fig. 24B shows end view 24B-24B from Fig. 24A. Distal ends 410, 416 are seen as preferably being parallel and mirror images of one another. Also, the preferable counter-rotating action may be seen by the directional arrows. Fig. 24C shows cross section 24C-24C from Fig. 24A. As shown, the relationship between first and second opening 414, 420, respectively, and first and second lumen 422, 424, respectively, may be seen in the figure. Lumens 422, 424 preferably run through the length of members 402, 404, respectively, and are in communication with openings 414, 420. A vacuum may be created in openings 414, 420 through lumens 422, 424, respectively, from the controlling device 406. In operation, members 402, 404 may be inserted trans-esophageally into a patient's stomach. A vacuum may then be created in first and second openings 414, 420 to engage a portion of the stomach interior lining. Once engaged, a modified pouch may be created from the interior lining in much the same manner as described for Figs. 23A to 23D, except the individual counter-rotating members 402, 404 do not form a split tube. The operation of the vacuum application and counter-rotation may be controlled through controlling device 406 which is preferably located outside the patient's body.

[0147] Fig. 25A shows yet another variation in vacuum device 432 shown inserted into stomach 430. Vacuum device 432 may be an endoscopic device inserted trans-esophageally into stomach 430 through esophagus 434. Device 432 may have vacuum member 438 and at least two grasping members 440, preferably disposed on either side of vacuum member 438. Once device 432 has been introduced into stomach 430, vacuum member 438 may be steered towards a desired area of interior lining 442, as seen in Fig. 25B which is a cross section view of device 432 attached to stomach interior lining 442. The desirable area of interior lining 442 may be located along greater curvature 436 or alternatively along lesser curvature 444, depending upon the desired results. In position, a vacuum may be activated in member 438 to draw a portion of interior lining 442 preferably between grasping members 440. As lining 442 is adhered to vacuum

member 438, grasping members 440 may be used to pinch and grasp the drawn portion of lining 442. Then, device 432 may be rotated in the direction of the arrow indicated in Fig. 25C to result in the formation of a modified lumen. Afterwards, grasping members 440 may be locked in place, disengaged from device 432, and left as an implant. Alternatively, lining 442 may be fastened to maintain the created lumen by any of the methods described herein and grasping members 440, along with the rest of device 432, may be removed from stomach 430.

Gastric Reduction Tools and Methods Using Volume Reduction Devices

[0148] Aside from the use of rotating and rotatable probes, gastric volume reduction devices may also be used as part of the present invention. Such volume reduction devices generally may be inserted into a stomach trans-esophageally through the use of, e.g., an endoscope. The reduction device may be used to draw or engage a portion of the interior lining of the stomach; the drawn or engaged portion may then be eventually removed, either actively or through natural processes.

[0149] Several examples of different possible variations on the gastric volume reduction devices are shown and described below. These variations are not intended to be limiting but are merely given as illustrative examples.

[0150] Fig. 26 shows an isometric view of a variation on the gastric volume reduction device in concentric tube device 450. Device 450 may have inner tube 452 defining lumen 454, which preferably runs throughout inner tube 452. Pusher sleeve 456 may be disposed concentrically over inner tube 452 such that pusher sleeve 456 may be allowed to slide freely along inner tube 452. Pusher sleeve 456 is also preferably disposed over inner tube 452 such that the distal end of inner tube 452 is open to allow ring 458 to be rolled or stretched onto the distal end. Ring 458 is preferably made of an elastic type material which would allow ring 458 to elastically cinch onto inner tube 452.

[0151] During use, Fig. 27A shows a view of concentric tube device 450 within stomach 460 preferably inserted through esophagus 462. The distal end of device 450, particularly inner tube 452, may be brought into position near a location of interior surface 464 where tissue may be desirably removed. As shown in Fig. 27B, once device 450 is in place, a vacuum may be actuated within

lumen 454. The vacuum may then draw a portion of withdrawn lining tissue 466 up into lumen 454, as seen in the cross section of device 450. While lining tissue 466 is held within lumen 454, pusher sleeve 456 may be pushed or urged distally along inner tube 452. As pusher sleeve 456 advances, it may also push or urge elastic ring 458 distally along inner tube 452 until ring 458 is pushed entirely off the distal end of inner tube 452 and onto a portion of lining tissue 466, as seen in Fig. 27C. Device 450 may then be removed from stomach 460 after ceasing the vacuum, thereby leaving lining tissue 466 with elastic ring 458. After time, as seen in Fig. 27D, pressure necrosis may cause lining tissue 466 and ring 458 to simply fall off from the rest of interior surface 464 to be passed normally through the rest of the patient's body. The action of drawing up and removing a portion of interior surface 464 may effectively reduce the overall volume of stomach 460, thereby reducing the available volume for the ingestion of foods. As such, this procedure may be repeated several times either sequentially or simultaneously until the overall volume of stomach 460 is reduced to a desirable volume depending upon the desired results.

[0152] Fig. 28 shows another variation on the gastric volume reduction device. As shown, an endoscope 474 preferably having grasping device 476, e.g., biopsy forceps, may be inserted into stomach 472. A ligating apparatus, e.g., ring stapler, zip tie, etc., either as part of endoscope 474 or as a separately introduced ligation device 478, is preferably also introduced within stomach 472. Forceps 476 and ligation device 478 may be used in conjunction with one another by, e.g., having forceps 476 grasp withdrawn tissue 480 and then having ligation device 478 tie or ligate tissue 480. Forceps 476 may then be used to excise and remove withdrawn tissue 480 above ties 482 to reduce the overall stomach volume. An example of a jaw structure which may be utilized is shown and described in U.S. Pat. No. 5,749,893 to Vidal *et al.*, which is incorporated herein by reference in its entirety. Alternatively, ligated withdrawn tissue 480 may be left attached to stomach 470 to be removed naturally by pressure necrosis. Several excisions may be performed in reducing stomach volume from, e.g., stomach 472 (as shown by the dashed lines) down to a final reduced stomach 470.

[0153] Fig. 29A shows yet another variation with tractive rollers 490. This device may have at least two rigid rollers 492, which are preferably elongated, connected to one another preferably at both ends by, e.g., elastic

members **494**. The connection of rollers **492** may create channel **496** therebetween through which tissue may be drawn. Fig. 29B shows rollers **492** with a portion of stomach interior surface **498** being drawn through channel **496** by a grasping device, e.g., forceps **500**. Meanwhile, rollers **492** may be maintained within the stomach by, e.g., retaining forceps **502**, which may be used to hold rollers **492** relative to interior surface **498**. Elastic members **494** may pinch rollers **492** together, thereby creating a zone of pressure necrosis in withdrawn interior surface **498**. Also, as interior surface **498** is drawn up through channel **496**, rollers **492** may contain a ratcheting device within to prevent surface **498** from rolling out back through channel **496**. Once the desired amount of surface **498** has been drawn, it may either be excised or simply left to be removed naturally by necrosis. Fig. 29C shows an alternative variation with ratcheted rollers **504**. Ratcheted rollers **504** may be operated in the same manner as described for rollers **492** but they preferably have a tractive surface to enhance traction between the tissue and the rollers **504**. Torquing device **506** may be used with ratcheted rollers **504** and may be introduced into the stomach endoscopically to mesh with one of rollers **504** for the purpose of causing it to rotate. Moreover, either rollers **492** or ratcheted rollers **504** may be used simply to gather stomach surface tissue to allow for fastening, e.g., suturing, stapling, etc.

Pyloroplasty Tools and Methods

[0154] Creating a smaller gastric pouch within the stomach may be accomplished by a variety of methods, as described above. To aid in the overall effect for the treatment of obesity, a pyloroplasty procedure may also be performed to enhance treatment. The pyloroplasty may be performed prior to (preferable), in conjunction with, or following the gastric reduction procedure. A pyloroplasty procedure typically results in the pyloric sphincter being rendered incompetent. However, in the case of treatments for GERD using the devices and methods described above, the pyloroplasty procedure as described herein may be omitted. Conventional pyloroplasty procedures may typically be performed surgically or through the use of standard peripheral angioplasty balloons, e.g., in the 7 mm range. However, in order to render a relatively healthy and normal pylorus permanently incompetent, a more aggressive procedure may be needed.

[0155] To accomplish this generally, a pyloroplasty device may be passed endoscopically through the esophagus, into the stomach, and preferably into position in or across the pylorus. Energy or a stimulus is then preferably applied to the pylorus to render it incompetent. Energy may be in the form of, e.g., heat, electrical, chemical, RF, etc., or a combination. Examples of chemical energy stimulus may comprise alcohol and sotrodecol. The stimulus may be in the form of, e.g., dilatation, cutting, ablation, viral, etc., or a combination. An example of a viral or chemical stimulus may be, e.g., a poison such as the botulinum toxin type A virus (Botox). An example of a method of use for Botox is described in U.S. Patent No. 5,437,291 to Pasricha *et al.*, which is incorporated herein by reference in its entirety. An incompetent pylorus may allow stomach contents to drain directly into the proximal duodenum with minimal resistance. Moreover, some of the mentioned pyloroplasty treatments may be selected or designed to last only for a specific time period, e.g., a week or several months, etc. For instance, the effects of simple dilatation or the injection of Botox may be designed to render the pylorus incompetent for only a few months, which may be a desirable time period for the patient to obtain the desired results of the procedure.

[0156] Several examples of different possible variations on pyloroplasty devices are shown and described below. These variations are not intended to be limiting but are merely given as illustrative examples.

[0157] Fig. 30 shows an isometric view of one variation of a dilatation device in balloon device **510** which may have angioplasty balloon **512** located near or at the distal end of catheter **514**. Angioplasty balloon **512** may be used alone to simply dilate the pylorus. Alternatively, exterior balloon surface **516** may have at least one and preferably several stimulating members **518** disposed about surface **516**. Stimulating members **518** are shown in the figure as cutting blades or wires, but alternatively, they may include electrodes, cryogenic dispensing probes or members, chemical dispensing probes, etc. Moreover, balloon **512** may alternatively be a dilation wire basket similarly disposed with stimulating members **518**.

[0158] Fig. 31 shows an isometric view of another variation in probe device **520**. Device **520** may have catheter or delivery member **524** with, e.g., probes **526**, which may extend from distal end **522**. Although three probes **526** are shown in the figure, at least one and up to several probes of varying thickness

and lengths may be used. Probes **526** may be retractable so that during delivery through, e.g., the esophagus or stomach, probes **526** may be withdrawn within distal end **522** and then extended when treating the pylorus. Probes **526** may be electrically connected to a voltage or power source located outside the patient's body to deliver electrical, RF, or heat energy to the pylorus. Alternatively, they may be configured like a needle to deliver chemical or biological stimuli to render the pylorus incompetent. For example, probes **526** may be used to inject chemicals, e.g., alcohol, sotrodecol, or other ablative chemicals, or biological stimuli, e.g., Botox virus or some other incapacitating virus, into the pylorus. Such stimulants may be carried within distal end **522**, delivery catheter **524**, or they may also be delivered from the proximal end of catheter **524** and injected through to probes **526**.

[0159] Other variations which may be used for the pyloroplasty procedure are shown in Figs. 32A and 32B. Fig. 32A shows sphincterotome arm **530** having a distal end **532**. Arm **530** may be bent as shown to allow cutting member **534** to be drawn between distal end **532** and a location proximal of distal end **532** along arm **530**. Another variation is seen in Fig. 32B where delivery member **536** may have an arcuate support member **538** to support cutting member **540**. The variations shown in Figs. 32A and 32B may be delivered via a catheter or endoscope trans-esophageally and through the stomach to the pylorus where either cutting member **534, 540** may be used to cut or saw into the tissue in or around the pylorus to render it incompetent. These particular variations of sphincterotomes shown in Figs. 32A and 32B may be manufactured by Medi-Globe Corporation, located in Tempe, AZ.

[0160] Fig. 33 shows stomach **550** with a distal portion of the wall of the lesser curvature removed for clarity. Device **520** may be delivered through esophagus **552** to a location proximal of pylorus **558**, e.g., first position **554**. If probes **526** were retracted during delivery, they may then be extended, as shown. Distal end **522** of device **520** may be advanced to, e.g., second position **556**, such that probes **526** may pierce pylorus **558** to deliver the stimulus.

[0161] Fig. 34A shows an isometric view of another variation with combination device **560**. Device **560** may have housing **562** on the distal end of delivery catheter or endoscope **564**. Housing **562** defines notch **566** which may be oriented perpendicularly relative to the longitudinal axis defined by endoscope

564. Notch **566** preferably has a geometry large enough to accommodate part of pylorus **558** and housing **562** may be tapered at its distal end to allow for easy insertion into the pylorus **558** during the procedure. Within notch **566** may be cutting blade **568** and on either side of blade **568** may be fasteners **570**, e.g., individual anchors, staples, etc. In operation, Fig. 34B shows housing **562** and endoscope **564** delivered through esophagus **552**. The wall of stomach **550** is partially cut away for clarity. Housing **562** may be inserted into pylorus **558**, then notch **566** is preferably aligned such that part of the pyloral sphincter lies within notch **566**. Alternatively, the pyloral tissue may also be drawn into notch **566** via a vacuum or grasping member. Once the pyloral tissue is within notch **566**, cutting blade **568** may be actuated to traverse notch **566** and sever part of the tissue of pylorus **558**. Fasteners **570** may then be deployed on either side of incision **572** to affix the incised tissue. The number of incisions **572** may vary depending upon the desired degree of pyloric disablement. Alternatively, an inflatable balloon may be attached on the back of notch **566** and inflated to push housing **562** into apposition with pylorus **558** and cause invagination of the tissue into notch **566**.

Anastomosis Tools and Methods

[0162] In addition to the tools and methods described above for gastric reduction and pyloroplasty procedures, an additional anastomosis gastric bypass procedure may also be performed to further enhance treatment. The anastomosis procedure may be performed preferably prior to, in conjunction with, or following the gastric reduction and pyloroplasty (if performed at all) procedures. In the case of treatments for GERD using the devices and methods described above, the anastomosis procedure as described herein may be omitted. The procedure generally involves endoscopically or laparoscopically creating a side-to-side anastomosis preferably from within the stomach and bowel and within the digestive tract. This procedure may be similar to the Roux-en-Y gastric bypass (RYGB) procedure but with minimal trauma. This procedure may also effectively bypass food from the stomach, past a proximal portion of the bowel, and preferably directly into a lower portion of the bowel. This bypassed portion may be considered a malabsorption zone.

[0163] A representative and normal gastro-intestinal system of a person is shown in Fig. 35 for comparison. Stomach 580 is shown with pyloric sphincter 582 near gallbladder 584 and attached to the proximal section of duodenum 586. The distal section of duodenum 586 is attached to the proximal section of jejunum 588, the distal section of which is further attached to the proximal section of ileum 590. Ileum 590 is then attached to ascending colon 592, which continues through to the transverse colon (which has been removed for clarity), and then to descending colon 594 and finally to rectum 596.

[0164] A gastro-intestinal system which may be modified by a preferable anastomosis procedure is shown in Fig. 36. Stomach 600 is shown in this variation as having been modified by creating modified pouch 602, which may be created by any of the methods and tools as described above. Esophagus 603 is preferably connected to a proximal end of pouch 602. As described above, the distal end of pouch 602 may be connected directly to pylorus 604 or alternatively, may be a blind-ended pouch and pylorus 604 is connected to the proximal end of duodenum 606. A first anastomosis 608 may be created preferably between modified pouch 602 and a section of digestive tract either from the distal duodenum 606 or proximal jejunum 610. First anastomosis 608 may be located in a range from about 20 to 50 cm from pylorus 604. A second anastomosis 614 may be created preferably between a section of duodenum 606 and a section of ileum 612. The second anastomosis 614 may be located in a range from about 15 to 55 cm from pylorus 604 or about 150 to 200 cm down along the length of the small intestines from pylorus 604. This procedure may allow for drainage of secretions created by stomach 600 to pass through pylorus 604 and secretions of bile and chyme from the pancreas and gallbladder 618 to pass through biliary duct 620 partly through duodenum 606 and then through second anastomosis 614 and directly into distal ileum 616 and out of the body. The bypassed stomach 600, pylorus 604, and proximal duodenum 606 may act as a malabsorption zone because sugars and fats which might normally be mostly absorbed in this zone may now be directly passed into the distal duodenum 606 or proximal jejunum 610.

[0165] During the anastomosis procedure, both first and second anastomoses 608, 614, respectively, may be created first. Duodenum 606 may then be closed off between the two anastomoses 608, 614. Then, depending upon

the length and size of the resulting modified stomach **602**, pylorus **604** may be closed off or left open, depending upon the desired result and which of procedures and tools are implemented. Finally, modified pouch **602** may be created after the anastomoses procedures. Alternatively, modified pouch **602** may be created prior to the anastomoses procedures, again depending upon the desired result and which of procedures and tools are implemented. If modified pouch **602** were created first, then the anastomoses procedure may be reversed to essentially end with the same result.

[0166] A conventional RYGB procedure is generally performed through a 6-8 inch incision extending from the end of the breastbone to just above the navel. However, the procedure described above may be performed entirely endoscopically or laparoscopically. Fig. 37 shows an isometric view of an assembly which may be utilized to achieve part of the procedure. Deployment device **630** may have anastomosis assembly **632** preferably connected by steerable length **634** to manipulation handle **636**. Assembly **632** may be steerable during insertion, preferably trans-esophageally and through the stomach, by steering grip **638** which may be located on manipulation handle **636**. Control by a physician or surgeon of manipulation handle **636** may be facilitated by handle **640**.

[0167] Anastomosis assembly **632** may have stapler housing **644** configured to fit intimately with distal element **646** preferably by a magnetic force, the use of which is described below. Distal element **646** is preferably tapered or rounded on one side and may have a coring anvil **648** on its opposing side. Coring anvil **648** may be tapered or rounded and may fit intimately into coring mate **650** which is preferably located near or at the center of stapler housing **644**. Stapler housing **644** may also house several staples loaded within staple slots **652**, which may be disposed circumferentially around coring mate **650** and may be actuated from the proximal end of length **634** by staple trigger **642**.

[0168] Fig. 38 shows a cross sectioned view of anastomosis assembly **632** mated with distal element **646** at first anastomosis **608** between modified pouch **602** and jejunum **610**. Part of the walls of modified pouch **602** and jejunum **610** have been removed for clarity. In creating first anastomosis **608**, distal element **646** may first be placed within the appropriate section of jejunum **610**. This may be done by orally passing distal element **646** through the esophagus, stomach, and then through the duodenum. Distal element **646** is preferably magnetized, either

by manufacturing distal element 646 from natural ferrous materials or artificially magnetizing it. Because of the magnetization, distal element 646 may be urged through the body and into place within the duodenum by, e.g., magnetic wands or magnetic pickups, which may be manipulated from outside the patient's body.

[0169] During or after placement of distal element 646, stapler housing 644, which may be attached to steerable length 634, may be introduced trans-esophageally into the stomach 602 and placed into position along stomach wall 660 at the desired site of first anastomosis 608. Once both stapler housing 644 and distal element 646 are in position, they may then be coupled together preferably by the magnetic force and attraction between the two. Moreover, the two may be brought into alignment either by alignment grooves (not shown) or by the mating of coring anvil 648 into coring mate 650. As the mating occurs, part of stomach wall 660 and intestinal wall 662 are preferably held or maintained between stapler housing 644 and distal element 646. To enhance the mating, fasteners may optionally be deployed from stapler housing 644 through staple slots 652 and preferably through both stomach wall 660 and intestinal wall 662 into distal element 646. Fig. 38 shows staples 667 deployed as fasteners, but they may comprise any type of mechanical fasteners as described above, as well as, e.g., grommet-type swages, snap lock fits, staples, screws, clips, and friction-fittings.

[0170] Once the fitting has been accomplished, the device may be left in apposition to maintain the position of stomach wall 660 and intestinal wall 662 for about one week. This may result in pressure necrosis of the tissue between stapler housing 644 and distal element 646 preferably causing the serosal layers of the gut to fuse, at which point the assembly may drop out and be passed, preferably leaving first anastomosis 608 behind. Alternatively, a coring device 664, which may be slidingly contained within stapler housing 644, may first be advanced through the center of stapler housing 644 and both stomach wall 660 and intestinal wall 662 to create first anastomosis 608. The remaining assembly may then be left to cause the pressure necrosis and fusing of tissue, as described. Another alternative may be to use stapler housing 644 and distal element 646 as a mechanism for a conventional end-to-end anastomosis (EEA) stapler. In this case, once they are aligned, a rod may be advanced through the center of the assembly to preferably lock distal element 646 to intestinal wall 662. The rod

may be drawn back, preferably pulling a distal stapler segment into stapler housing **644**. This action may cause staples to fire and a circumferential blade to cut out the center of the staple ring, thereby creating an anastomosis.

[0171] To create second anastomosis **614**, a similar approach may be taken as for creating first anastomosis **608**. An example of another magnetic anastomosis device which may also be used in this procedure is shown and described in U.S. Pat. No. 5,690,656 to Cope *et al.*, which is incorporated herein by reference in its entirety. Fig. 39 shows a portion of duodenum **606** juxtaposed to a portion of ileum **612** and distal ileum **616** with part of the intestinal walls removed for clarity. In this variation, proximal element **670** may be used and is preferably a magnetized mating element for distal element **646**. Distal element **646** may first be urged to the desired location preferably in ileum **612** by, e.g., magnetic wands or magnetic pickups, which may be manipulated from outside the patient's body, in the same manner as above. During or after placement of distal element **646**, proximal element **670** may also be delivered or urged to the desired location in the same manner. Once both elements **646, 670** are in position, they are preferably mated together by a magnetic force. The mating may optionally be enhanced by fasteners, e.g., staples **667**, to hold both elements **646, 670** in position. The intestinal wall inbetween may be cored, as described above, but it may also be simply left to undergo pressure necrosis between elements **646, 670** eventually causing the serosal layers of the gut to fuse, at which point elements **646, 670** may drop out and be passed, preferably leaving second anastomosis **614** behind.

Gastric Reduction Tool Overtube System

[0172] In using any one of the gastric reduction tools as described above, e.g., those as shown in Figs. 7A, 9A-14, 26, 30-32B, and 34A, the treatment of a hollow body organ may require multiple passes by the tools used. Accordingly, to facilitate patient treatment, an overtube assembly may be used in conjunction with those tools. Fig. 40A shows an isometric view of overtube assembly **680** which can be used to efficiently affect treatment with minimal discomfort to a patient. Overtube assembly **680** is preferably comprised of overtube member **682** which may be inserted into the hollow body organ, e.g., the stomach, through the esophagus of the patient. A working lumen **684** may be defined through overtube

682 from proximal end 698 at overtube module 692 to distal end 696 of overtube 682. At distal end 696, at least one window 700, and preferably two or more windows 700 are preferably defined opposite of one another in this variation, as shown. Windows 700 are preferably defined in the shape of slots near or at the distal end 696 of overtube 682. The lengths and widths of slots 700 may vary and are preferably long enough to approximate a desired length of a boundary or junction line within the stomach, as discussed below. The stomach is comprised of at least three layers including the inner mucosal layer (mucosa), a muscular layer exterior to the mucosa (muscularis mucosae), and an exterior serosal layer (serosa). The widths of window 700 are preferably wide enough to accommodate at least two layers of the stomach interior lining and more preferably all the layers of the stomach. Illustrative widths of window 700 may range anywhere from about 0.320 cm (0.125 in.) to 0.950 cm (0.375 in.) and may range anywhere in length from about 0.635 cm (0.250 in.) to 15.25 cm (6 in.). Overtube assembly 680, including the variations described herein, may be used to effect a variety of treatments in combination with the variety of tools and methods as described above.

[0173] Several aspects of the present invention were arrived at after experimentation with stomach tissue and the challenges of acquiring and securing such tissue reliably. In particular, it is desirable that the assembly 680 consistently approximate the tissue such that when fasteners are delivered, as described herein, they consistently reach the outer layers, or fibrous layers, of the stomach wall, such as the muscularis and serosa. The present invention may assist in this by acquiring tissue such that these fibrous layers intersect or overlap within working lumen 684, allowing them to be secured together. Once these fibrous layers are fastened appropriately, they will adhere, fuse, or scar over to affect the desired fastening. The tissue is preferably maintained in apposition with, e.g., the two folds, for 2-4 weeks to affect healing, but that fusion of the tissue may take place as soon as 5-10 days following a procedure. If tissue folds are fastened inconsistently, or if the fasteners only penetrates the less fibrous tissue, such as the mucosa, complications such as gastric erosion, ulceration, and failure of the secured walls may result.

[0174] The entire length of overtube 682, or at least a majority of the length of the device, is preferably flexible enough to be inserted within the body

through, e.g., the esophagus, and conform at least partially to the curvatures within the body. For example, overtube **682** may range in length from about 40 cm (15.75 in.) to 100 cm (39.40 in.), and is preferably about 80 cm (31.50 in.). The overall diameter of overtube **682** may range from about 5 mm (0.20 in.) to 30 mm (1.18 in.), and preferably from about 15 mm (0.60 in.) to 17 mm (0.70 in.). Alternatively, the length of overtube **682** may be sufficiently flexible yet define a bendable region **694** near distal end **696** which may be more flexible than the rest of overtube **682**. Bendable region **694** may have a flexibility such that it may be manipulated or bent in arbitrary shapes either actively by the physician or surgeon or passively by an endoscopic device inserted within overtube **682**. Examples of tubular structures which are actively manipulatable and selectively rigidizable may include those found in U.S. Patent Nos. 5,624,381 (Kieturakis) and 4,790,294 (Allred, III et al.), among others.

[0175] If passively manipulatable, overtube **682** may be made from any variety of biocompatible materials which provide sufficient structure to the device yet allows for the device to be bent, e.g., thermoset or thermoplastic materials such as PTFE, FEP, polyurethane, PVC, silicone, Nylon, pellethane, etc. Alternatively, overtube **682** may be preformed to have a bent or arcuate configuration near or at distal end **696**. When inserted into a patient, a straightening mandrel **702** or endoscopic device may be positioned within the curved region **694** to maintain a straightened configuration, as shown in Fig. 40B. When overtube **682** has been desirably positioned within the patient, the straightening mandrel **702** may be withdrawn from the device leaving the overtube **682** to reconfigure itself to its preformed shape. Another alternative is to have overtube **682** remain passively manipulatable and to have the insertable mandrel preformed into the curved configuration **704**, as also seen in Fig. 40B. In this case, the overtube **682** may be inserted in its straightened configuration and the curved mandrel **704** may be inserted through the overtube **682** in a constrained and straightened configuration through overtube **682**. When curved mandrel **704** reaches the distal end **696**, mandrel **704** may be allowed to curve into its preformed shape which may force overtube **682** to reconfigure with the mandrel **704**. The mandrel **704**, in this case, is preferably made of a shape memory alloy, e.g., a nickel-titanium alloy such as Nitinol. In either case, the mandrel may be

inserted within an internal working channel of overtube 682 or along a exterior channel defined along the outer surface of overtube 682.

[0176] Overtube 682 may also be made to have a proximal portion which is relatively stiffer than bendable region 694 or distal end 696. Also, overtube 682 may have a wall thickness which depends upon the type of material used for construction which is sufficient to maintain the structural integrity of the device during use. For example, a wall thickness ranging from about 0.80 mm (0.032 in.) to 6.35 mm (0.250 in.) may be used.

[0177] A separate drive tube 688 is preferably inserted within lumen 684 of overtube 682 through overtube module 692. Drive tube 688 is preferably a tubular member which has an outer diameter which is smaller than the inner diameter of overtube 682. Drive tube 688 may be fabricated from the same or a similar material as overtube 682 or any of the other materials described above. There is preferably enough clearance between tubes 682, 688 such that drive tube 688 is freely adjustable within overtube 682, i.e., freely movable longitudinally and/or rotationally within overtube 682. Drive tube 688 is made to have a lumen defined through the tube 688 from a proximally located insertion port 686 to the distal end of tube 688. To prevent drive tube 688 from being pushed entirely through overtube 682, drive tube stop 690 may be located at the proximal end of tube 688. Stop 690 may be any projection, e.g., an enlarged diameter disk, which abuts against overtube module 692 to prevent the further advancement of drive tube 688 within overtube 682. Stop 690 may be made from a material similar to tube 688 or it may be made from a biocompatible metallic material such as stainless steel, platinum, etc., and attached to drive tube 688.

[0178] A detailed assembly view of the distal end 696 of overtube assembly 680 is shown in Fig. 41 with the wall of overtube 682 partially removed for clarity. As shown, overtube 682 may have drive tube 688 inserted within lumen 684 and extending towards the distal end of overtube 682. An endoscope 710, which may comprise any conventional endoscopic device preferably having optical viewing capabilities (e.g., through optical fibers), may be inserted within drive tube 688 at its proximal end through insertion port 686. Endoscope 710 may be advanced distally through both overtube 682 and drive tube 688 to extend beyond the distal end 696 of overtube 682 to examine and/or identify tissue regions of interest.

[0179] Also preferably located within lumen 684 near or within the distal end 696 of overtube 682 is fastener 714. Fastener 714 is preferably located distally of drive tube 688 and may be configured to have a proximal end 716 for engagement with fastener engagement area 712 of drive tube 688. It may be further configured to have a tapered distal tip 718 for piercing tissue as fastener 714 is advanced distally. As shown, fastener 714 may be configured in a spiral or helical shape having at least two revolutions and it may be configured to form an inner diameter which is large enough to allow endoscope 710 to pass therethrough uninhibited. During advancement of overtube 682 into the body or during examination of the tissue with endoscope 710, fastener 714 may be maintained within lumen 684 by some temporary attachment device against the inner wall of lumen 684. Preferably, however, fastener 714 may be attached via proximal end 716 to area 712 until fastener 714 is deployed into the tissue. Proximal end 716 may be temporarily connected to area 712 via a conventional mechanical engagement, such as a friction fit or a détente located within area 712, or via an electrically-actuated joint or connection, e.g., an electrically-erodable joint.

[0180] Once fastener 714 is to be deployed into the tissue, drive tube 688 with fastener 714 connected thereto, may be advanced distally through lumen 684 and drive tube 688 may then be rotated via a proximally actuated torquing force. The torquing force may be actuated either manually or automatically with a motorized assembly (not shown). As drive tube 688 rotates about its longitudinal axis, fastener 714 also rotates and advances into the tissue region of interest while fastening the tissue in a manner similar to a screw.

[0181] Fastener 714, which is preferably in the shape of a helix or spiral, may optionally have a tapering width or diameter. The first few turns or coils of fastener 714 may have the same or similar diameter than the remaining tapering coils; this may enable distal piercing end 718 to engage the tissue and may also allow fastener 714 to be advanced at the desired orientation through the tissue. Fastener 714 preferably maintains a parallel orientation with overtube 682 during delivery into the tissue, i.e., a longitudinal axis defined by fastener 714 is preferably parallel, or close to parallel, with the longitudinal axis defined by overtube 682. Moreover, the outer diameter of the first few turns or coils may be the same diameter, or slightly less than, the inner diameter of overtube 682. This

may further enable fastener 714 to be advanced through lumen 684 at the proper orientation prior to engaging the tissue.

[0182] Fastener 714 may be made of a bioabsorbable or biocompatible material, as described herein such as a polymer or superelastic alloy, or a metal, e.g., stainless steel, platinum, titanium, etc., and may be integrally formed with barbs or whisker-like filaments protruding along its length to help prevent fastener 714 from backing out once it has been engaged within the tissue. Fastener 714 may be the same or a similar fastener as screw 289 described above. It may also be similar to the spiraling suturing needle or fastener shown and described in U.S. Patent No. 5,330,503 to Yoon, which has been incorporated above.

[0183] Fig. 42A shows a detailed isometric view of the proximal assembly of overtube assembly 680 with endoscope 710 inserted within insertion port 686. The shaft of endoscope 710 may be seen almost fully inserted within assembly 680 up to endoscope handle 720 through insertion port 686 located in drive tube stop 690. Endoscope 710 may be selectively advanced and withdrawn by the physician or surgeon into assembly 680 or it may be withdrawn completely from insertion port 686 during a procedure to allow for the insertion of other tools or devices.

[0184] Also seen extending from overtube module 692 is fluid port 722 which may be included as part of overtube assembly 680. Fluid port 722 is a port which is in fluid communication with working lumen 684 defined within overtube 682 and may be in fluid communication through, e.g., a hose, to a pump which may provide the negative pressure to create a vacuum within lumen 684. Although a single fluid port 722 is shown, any number of ports may be used. If multiple ports are utilized, each port may be fluidly connected to the same or a different pump. Furthermore, fluid port 722 and any of the other fluid ports, if used, may also be fluidly connected to positive pressure pumps either in parallel or alternatively switched. Alternatively, the same pump may be used to provide both negative and positive pressure. Positive pressure pumps may be used to provide the adequate pressure to deliver fluids through fluid port 722 into lumen 684 for delivery of, e.g., therapeutic drugs, saline, or gases such as nitrogen for insufflating an area within the body, among other fluids.

[0185] Any number of markers 744 may be placed upon the overtube assembly 680, e.g., upon overtube module 692 as shown in Fig. 42A. Markers

744 may be placed upon module 692 to correspond with the circumferential location of windows 700 and may thus be used as a guide for aligning windows 700 within the patient. Overtube 682 may be manipulated and rotated from outside the body to align markers 744 with a landmark located on the patient, e.g, alignment with the patient's nose. In this manner, windows 700 of overtube 682 may be desirably positioned within the patient through external manipulation without the need to align windows 700 by direct visualization within the patient.

[0186] As drive tube 688 may be selectively advanced and withdrawn relative to overtube 682 and also relative to endoscope 710, a fluid-tight seal is preferably maintained between overtube module 692 and drive tube 688. This fluid-tight seal is preferably sustained in order to maintain the pressure (positive or negative pressure) within lumen 684 through fluid port 722, and more specifically within the communication lumen 728 which is created between the outer surface of drive tube 688 and the inner surface of overtube 682, as seen in Fig. 42B, which shows a cross-sectioned profile of the assembly of Fig. 42A. and may be accomplished by any number of conventional sealing methods. For instance, overtube module 692 may be gasketed 726 against the outer surface of drive tube 688 to maintain the seal between the two, as also seen in Fig. 42B. Alternatively, other types of seals using, e.g., sealing gels, ferrofluidic seals, etc., may be utilized. In addition to maintaining fluid-tight seals, guard 724 may also be included in assembly 680 to provide structural strength to the area of tissue through which assembly 680 is inserted and also to prevent overtube 682 from being pinched or crushed. For instance, if assembly 680 were inserted orally into the esophagus of a patient, guard 724 may be inserted into the mouth of the patient and used as a bite guard to prevent the patient from biting down on overtube 682. Also, guard 724 would also ensure a smooth pathway for overtube 682 through the mouth of the patient.

[0187] Fig. 43 shows a schematic of one example of assembly 680 in use within a patient 730. As shown, assembly 680 may be inserted orally through mouth 732 of patient 730 and advanced within esophagus 734 until distal end 696 is advanced beyond gastro-esophageal junction 738 and into stomach 736. Once in stomach 736, distal end 696 may be actively or passively positioned by the physician or surgeon about bendable region 694 until the device has been desirably positioned. Then pump 742, which is preferably in fluid communication

with communication lumen 728 within overtube 682 through fluid tube 740, may be activated to create a vacuum within overtube 682 to draw portions of the identified tissue within windows 700. A vacuum force of about 15 to 20 inch-Hg may be utilized, although the amount of vacuum pressure may be varied depending upon the size of the windows 700 and the amount of tissue to be drawn into overtube 682. As mentioned above, pump 742 may also be used as a positive pressure pump which may then be used to deliver therapeutic agents, fluids, or gases through tube 740 and overtube 682 for dispersion within stomach 736.

[0188] Fig. 44 shows a cross-sectioned end view of overtube 682 within stomach lumen 764 of stomach 736 once the vacuum has been created within working lumen 684. As shown, overtube 682 may be positioned adjacent relative to lesser curvature 750 of stomach 736; however, overtube 682 may alternatively be positioned closer to greater curvature 760 or anywhere inbetween depending upon the desired treatment and effects upon the patient. For instance, overtube 682 is preferably positioned closer to lesser curvature 750 prior to approximating the walls of stomach tissue such that a modified lumen may be created by overtube assembly 680 leading directly from esophagus 734 to the pyloral sphincter of stomach 736. Alternatively, overtube 682 may be positioned closer to greater curvature 760 for the treatment of GERDs. As seen, overtube 682 may acquire the lining of the stomach and draw several layers of stomach tissue, i.e., mucosal layer 754, muscular layer 756, and serosal layer 758, into lumen 684 through windows 700 while creating creases 762 within the outer surface of stomach 736 which may denote where stomach 736 has been invaginated. All the layers of stomach 736 need not be invaginated, but at least two layers are preferably drawn in, and more preferably all the layers, so that adequate tissue exists within lumen 684 for approximating the walls of stomach 736. The vacuum is preferably maintained until the invaginated tissue 752 is drawn within lumen 684 such that a fastener, as described further below, may grasp both, or several, regions of invaginated tissue 752 and approximate or maintain the tissue.

[0189] Fig. 45 shows an isometric view of overtube 682 within stomach 736 with the stomach and overtube walls partially removed for clarity. As shown, overtube 682 may be inserted, as described above. Once desirably positioned within stomach lumen 764, a vacuum may be created within working lumen 684 of overtube 682 and tissue 752 may become invaginated within lumen 684

through windows **700**, as shown. Once the invaginated tissue **752** has been adequately drawn into overtube **682**, any number of flexible endoscopic stapling devices, as described herein, may be used to hold the suctioned tissue together.

[0190] Alternatively, fastener **714** may be advanced distally while rotating it using drive tube **688**, which is shown as having been withdrawn. As fastener **714** is rotatingly advanced, its piercing distal tip **718** may wind into and around invaginated tissue **752** in an alternating helical or spiral pattern until fastener **714** has been fully advanced into tissue **752**. Fastener **714** may be configured to have an inward bias such that once fastener **714** has been deployed within tissue **752**, the coils of fastener **714** bias inwardly such that the fastener **714** diameter shrinks and fastener **714** elongates. A single fastener **714** may be used to bind the apposing walls of tissue **752** within stomach **736**, in which case fastener **714** is preferably an elongated fastener sufficiently long enough to bind the tissue. Alternatively, multiple fasteners **714** may be fastened one after another to form a continuous fixation line. In which case overtube **682** may be advanced to a distal position within stomach **736** and a portion of the tissue walls may be fastened, as described above. Overtube **682** may then be pulled proximally a short distance within stomach lumen **764** and repositioned.

[0191] While maintaining the position of overtube **682** within stomach lumen **764**, drive tube **688** may be withdrawn from overtube lumen **684** and another fastener **714** may be inserted within overtube **682** and advanced distally to fasten another portion of the tissue wall. This process may be repeated as necessary until the desired length or locations of tissue have been fastened. An alternative configuration for the drive tube may include a clamping device for holding the approximated tissue to one another while fastening the tissue together, as discussed in further detail below.

[0192] A biodegradable plug, such as plug **292** described above, may optionally be placed into the distal end of overtube **682**, also in much the same manner as above, prior to insertion into the patient and is preferably made of a biocompatible biodegradable material, e.g., biodegradable polymers such as polylactide, polyglycolide, and their copolymers. The plug may be alternatively made from a non-biodegradable material and may simply pass after the procedure. The plug may aid in maintaining a vacuum seal through windows **700** during the fastening procedure.

[0193] Figs. 46A and 46B show detailed isometric and end views of one variation of distal end 696 of overtube 682. As shown in Fig. 46A, windows 700 may be formed into slots, as also described above. Fig. 46B shows an end view with invaginated tissue 752 projecting into lumen 684. The apposed portions of tissue 752 may be drawn into overtube 682 via a vacuum force until the tissue 752 portions contact one another at contact area 770.

[0194] Another variation for configuring the distal end of the overtube is shown in Figs. 47A and 47B. As seen in Fig. 47A, an isometric view of overtube offset variation 780 may have the apposed windows 782, 782' defined along the length of overtube 780 near or at the distal end, as described above. However, the working lumen within overtube 780 may have dividing wall 786 formed within and extending diametrically to form two separate lumens 784, 784'. Dividing wall 786 is preferably formed within the distal end portion of overtube 780 and may be as long as windows 782, 782'. Alternatively, wall 786 may extend throughout the length of overtube 780. Each separated lumen 784, 784' may open to a window 782, 782', respectively. As shown in Fig. 47B, apposed walls of tissue 788, 788' may be drawn into respective lumens 784, 784' until they overlap one another between dividing wall 786. To fasten and/or approximate the apposed walls of tissue 788, 788', an endoscope or flexible fastening device may be used to fasten the tissue to one another. Alternatively, longitudinally-shaped channels 789 may optionally be defined within wall 786 near where dividing wall 786 joins overtube 780 wall. A helically or spirally-shaped fastener, as described above, may then be used with this variation as well. This variation 780 may or may not be used with a separate endoscope disposed within the working lumen.

[0195] Fig. 48A shows an isometric view of overtube variation 780 inserted within stomach lumen 764 with the walls of both stomach 736 and overtube 780 partially removed for clarity. As shown, the invaginated and overlapping stomach lining 788, 788' can be seen within first and second lumen 784, 784' (dividing wall 786 has been removed for clarity only). As the overlapping tissue 788, 788' is held relative to one another, fastening assembly 806 may be advanced within overtube 780 to where the approximated tissue is positioned. Fastening assembly 806 may be any one of the fastening devices or endoscopic stapling assemblies as described above. The example shown comprises shaft 808 with fastening anvil 810 pivotally attached about pivot 812.

Fastening assembly 806 may be manipulated from its proximal end to clamp the tissue 788, 788' between anvil 810 and fasteners 814. As described above, fasteners 814 may be in the form of staples, rivets, or other mechanical fasteners as described herein, which may be housed within shaft 808. To secure the tissue to one another, fastening assembly 806 may be clamped onto overlapping tissue 788, 788' to create a fixation zone or region 816. Fig. 48B shows tissue 788, 788' having been attached together over fixation region 816 and fastening assembly 806 having been withdrawn from overtube 780.

[0196] Figs. 49A to 50B show another variation for configuring the distal end of the overtube. Fig. 49A shows an isometric view of overtube 790 which has several alternating windows. On apposing sides of overtube 790, first channel 792 and second channel 792' may be defined extending longitudinally along the distal end of overtube 790. Along first channel 792, a number of windows 794 may be defined which are preferably evenly spaced from one another with first channel 792 running throughout. On the apposed side, second channel 792' may be defined with a number of windows 794' which are also evenly spaced from one another. Windows 794 and 794' may be similarly shaped but are preferably alternating with apposed windows to allow tissue to be drawn within lumen 796 in an overlapping manner. Fig. 49B shows an isometric view of the overtube 790 from Fig. 49A with half the wall removed for clarity. Fig. 50A shows a side view of overtube 790 and first channel 792 while Fig. 50B shows a side view of the other side of overtube 790 and second channel 792'. The number of windows in either channel 792, 792' is not intended to be limiting but any number of alternating windows may be incorporated within overtube 790 depending upon the desired application and results.

[0197] Fig. 51 shows a cross-sectioned side view of overtube 790 from Figs. 49A to 50B showing the invagination of tissue within. As seen, invaginated tissue 800, 800' may be drawn into lumen 796 through the respective first and second windows 794, 794'. Once drawn within, the overlapping tissue 800, 800' may be fastened to one another using spiral fastener 714 as described above using a drive tube. Alternatively, and as shown, fasteners 802, each preferably having tapered or sharpened distal tips 804, may be driven distally from the proximal end of overtube 790 into each adjacent region of invaginated tissue 800, 800' to fasten them together. Once fastened, overtube 790 may then be withdrawn from the area

by simply retracting overtube **790** while maneuvering the fastened tissue through first and second channels **792, 792'**. Although two fasteners **802** are shown, any number of fasteners may be utilized depending upon the desired results. Additionally, to aid in preventing the fasteners from backing out of the tissue or from being dislodged, barbs or whisker-like filaments may be formed along its length to protrude and to engage the tissue once the fasteners are in place within the tissue.

[0198] The applications of the apparatus and methods of use discussed above are not limited to regions of the body but may include any number of further treatment applications. Other treatment sites may include areas or regions of the body around organ bodies. Modification of the above-described assemblies and methods for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the art are intended to be within the scope of the claims.

CLAIMS

We claim:

1. A method for forming a lumen from an interior of an organ comprising:

placing at least a first anchor on a first area of the interior;

placing at least a second anchor on a second area of the interior; and

drawing at least the first anchor and at least the second anchor in proximity to each other such that the lumen is formed.

2. The method of claim 1 wherein the organ comprises a stomach.

3. The method of claim 1 wherein the first anchor comprises a fastener selected from the group consisting of staples, ratcheted wires, zip ties, clips, tags, eyelets, crimps, and screws.

4. The method of claim 1 wherein the second anchor comprises a fastener selected from the group consisting of staples, ratcheted wires, zip ties, clips, tags, eyelets, crimps, and screws.

5. The method of claim 1 wherein placing at least the second anchor on the second area of the interior comprises placing the second anchor in apposition to the first anchor within the organ.

6. The method of claim 1 wherein drawing at least the first anchor and at least the second anchor in proximity comprises passing a suture through each of the anchors and pulling the suture such that the first area and the second area of the interior are drawn together.

7. The method of claim 6 wherein the suture is passed through each of the anchors in a zig-zag manner.

8. The method of claim 1 wherein the first anchor and the second anchor each comprise a crimping member.

9. The method of claim 8 wherein each of the crimping members are configured to interlock together.

10. The method of claim 1 further comprising interlocking the first anchor to the second anchor such that the first area and the second area of interior surface are in apposition.

11 A fastening device for securing tissue in an organ interior comprising:

a helical member having a distal end and a proximal end with a coiled length therebetween,

wherein at least two coils at the distal end of the helical member each comprise a diameter which is equal,

the helical member being configured for delivery through a lumen defined through a length of an elongate member having a proximal end and a distal end.

12 The fastening device of claim 11 wherein the diameter of the two coils is larger than a diameter of a proximal coil.

13 The fastening device of claim 11 wherein the coiled length is tapered.

14 The fastening device of claim 11 wherein the diameter of the two coils is equal to a diameter of the lumen of the elongate member.

15 The fastening device of claim 11 wherein the distal end of the helical member is configured to pierce tissue.

16 The fastening device of claim 11 wherein the helical member is configured to maintain an orientation parallel to a longitudinal axis of the elongate member during delivery.

17 The fastening device of claim 11 wherein the coiled length is at least partially covered with securing members.

18. The fastening device of claim 17 wherein the securing members are selected from the group consisting of barbs and whisker-like filaments.

19. The fastening device of claim 11 wherein the helical member comprises a bioabsorbable or biocompatible material.

20. The fastening device of claim 19 wherein the bioabsorbable or biocompatible material is selected from the group consisting of polymers and superelastic alloys.

21. A marking device for marking a location on an interior surface within an organ comprising:

an elongate member having a proximal end and a distal end with a length therebetween,

the length defining a shape which approximates a lumen to be formed from the interior surface,

the length further defining at least one dye port, the dye port being configured to contact an area of the interior surface and deliver dye.

22. The marking device of claim 21 further comprising an inflatable balloon at the distal end of the elongate member.

23. The marking device of claim 21 wherein the length further defines at least one vacuum port in communication with the distal end of the elongate member.

24. The marking device of claim 21 wherein the length further defines a plurality of additional dye ports.

25. The marking device of claim 21 wherein the organ comprises a stomach.

26. The marking device of claim 21 wherein the elongate member is curved.

27. The marking device of claim 26 wherein the curved elongate member is configured to follow a lesser curvature of a stomach.

28. The marking device of claim 26 wherein the dye port is defined along an outer radius of curvature of the curved elongate member.

29. The marking device of claim 21 wherein the elongate member is configured to be delivered to the interior surface trans-esophageally.

30. A method of marking a location on an interior surface within an organ comprising:

inserting a marking device into the organ, the marking device comprising an elongate member having a proximal end and a distal end with a length therebetween, the length defining a shape which approximates a lumen to be formed from the interior, the length further defining at least one dye port, the dye port being configured to contact an area of the interior surface and deliver dye;

reducing a volume of the organ such that the interior surface contacts the elongate member;

passing a dye through the dye port; and

increasing the volume of the organ.

31. The method of claim 30 wherein reducing a volume of the organ such that the interior surface contacts the elongate member comprises removing contents of the organ via a vacuum.

32. The method of claim 31 wherein the vacuum is created in a vacuum port defined along the length of the elongate member.

33. The method of claim 30 wherein passing a dye through the dye port further comprises marking the area of the interior surface in contact with the dye.

34. The method of claim 30 wherein the dye comprises a biocompatible dye selected from the group consisting of methylene blue, thionine, acridine orange, acridine yellow, acriflavine, quinacrine and its derivatives, brilliant green, gentian violet, crystal violet, triphenyl methane, bis naphthalene, trypan blue, and trypan red.

35. A method for forming a lumen from an interior of an organ comprising:

delineating a first boundary of the lumen on a first area and a second boundary of the lumen on a second area of the membrane using the method as described in claim 30;

removing the marking device from the organ;

placing at least a first anchor along the first boundary;

placing at least a second anchor along the second boundary; and

drawing at least the first anchor and at least the second anchor in proximity to each other such that the lumen is formed.

36. The method of claim 35 wherein the first anchor comprises a fastener selected from the group consisting of staples, ratcheted wires, zip ties, clips, tags, eyelets, crimps, and screws.

37. The method of claim 35 wherein the second anchor comprises a fastener selected from the group consisting of staples, ratcheted wires, zip ties, clips, tags, eyelets, crimps, and screws.

38. The method of claim 35 wherein drawing at least the first anchor and at least the second anchor in proximity comprises passing a suture through each of the anchors and pulling the suture such that the first area and the second area of the interior surface are drawn together.

39. The method of claim 38 wherein the suture is passed through each of the anchors in a zig-zag manner.

40. The method of claim 35 wherein the first anchor and the second anchor each comprise a crimping member.

41. The method of claim 40 wherein each of the crimping members are configured to interlock together.

42. A device for forming a lumen from an interior of an organ comprising:

a tissue adhering member having a proximal end and a distal end with a length therebetween, the member having at least two releasably adherable regions for releasably positioning a first area of the interior near a second area of the interior,

whereby the lumen is formed upon fastening the first area to the second area.

43. The device of claim 42 further comprising at least one fastener disposable within the tissue adhering member for fastening the first area to the second area.

44. The device of claim 42 wherein the first area is positioned adjacent to the second area.

45. The device of claim 42 wherein the first area is in apposition to the second area.

46. The device of claim 42 wherein the tissue adhering member defines a slot along the length, the slot being adapted to receive a retractable septum.

47. The device of claim 46 wherein the retractable septum defines at least one surface adapted to abrade an adjacent portion of the interior.

48. The device of claim 47 wherein the adjacent portion of the interior surface is abraded by the retractable septum using a method selected from the group consisting of cutting, scoring, heating, freezing, and chemical ablation.

49. The device of claim 42 wherein each of the two releasably adherable regions are separated by an angle between about 20° to 180° about a longitudinal axis defined by the length.

50. The device of claim 49 wherein the two releasably adherable regions are separated by an angle between about 90° to 180°.

51. The device of claim 42 wherein the first area and the second area are adhered to the tissue adhering member via a vacuum created in each of the two releasably adherable regions.

52. The device of claim 51 wherein each of the two releasably adherable regions are in fluid communication with a common channel defined within the tissue adhering member.

53. The device of claim 42 further comprising a delivery member having a proximal end and a distal end with a length therebetween, the tissue adhering member being attached to the distal end of the delivery member.

54. The device of claim 53 wherein the tissue adhering member is in fluid communication with the proximal end of the delivery member.

55. The device of claim 43 further comprising a wedge slidingly disposed within an interior channel defined by the tissue adhering member, the wedge being adapted to urge the fastener from an open first configuration to a closed second configuration.

56. The device of claim 55 wherein the fastener comprises a mechanical fastener selected from the group consisting of C staples, U staples, clips, and tags.

57. The device of claim 55 further comprising a wire attached to the wedge.

58. The device of claim 42 wherein the length of the tissue adhering member is straight.

59. The device of claim 42 wherein the length of the tissue adhering member defines an arc approximating a curvature of the organ.

60. The device of claim 42 wherein a geometry of the tissue adhering member is adjustable.

61. The device of claim 42 wherein the distal end of the tissue adhering member flares away from a curvature of the organ.

62. The device of claim 42 wherein the organ comprises a stomach.

63. The device of claim 62 wherein the tissue adhering member is adapted to be inserted into the stomach endoscopically via an esophageal passageway.

64. The device of claim 43 wherein the fastener comprises a screw having a helical shape.

65. The device of claim 64 wherein a diameter of a distal end of the screw is larger than a diameter of a proximal end of the screw.

66. The device of claim 65 wherein a length between the distal end of the screw and the proximal end of the screw is tapered.

67. The device of claim 64 wherein at least two coils at a distal end of the screw each comprise a diameter which is equal.

68. The device of claim 64 wherein a distal end of the screw is configured to pierce tissue.

69. The device of claim 64 wherein the screw is at least partially covered with securing members.

70. The device of claim 69 wherein the securing members are selected from the group consisting of barbs and whisker-like filaments.

71. The device of claim 64 wherein the screw comprises a bioabsorbable or biocompatible material.

72. The device of claim 71 wherein the bioabsorbable or biocompatible material is selected from the group consisting of polymers and superelastic alloys.

73. The device of claim 66 wherein the screw is configured to alternatingly pierce a first area of tissue and a second area of tissue while approximating the first area of tissue and the second area of tissue together.

74. The device of claim 43 further comprising a plurality of additional fasteners, each of the fasteners being configured to fasten the first area to the second area while juxtaposed linearly to form a continuous fixation line.

75. A method for creating a lumen from an interior of an organ comprising:

releasably adhering a first area of the interior to a tissue adhering member;

displacing the first area of the interior via the tissue adhering member;

releasably adhering a second area of the interior to the tissue adhering member such that the first area is positioned near the second area; and,

fastening the first area to the second area to form the lumen.

76. The method of claim 75 wherein the first area and the second area are releasably adhered to the tissue adhering member via a vacuum created in at least two releasably adherable regions defined in the tissue adhering member.

77. The method of claim 75 wherein the first area is positioned adjacent to the second area.

78. The method of claim 75 wherein the first area is in apposition to the second area.

79. The method of claim 75 wherein releasably adhering a second area of the interior surface to the tissue adhering member such that the first area is positioned near the second area further comprises removing a septum disposed in the tissue adhering member such that the first area contacts the second area.

80. The method of claim 79 further comprising inducing a healing response in the first area or the second area while removing the septum.

81. The method of claim 79 further comprising abrading the first area or the second area while removing the septum.

82. The method of claim 81 wherein abrading the first area or the second area comprises a method selected from the group consisting of cutting, scoring, heating, freezing, and chemical ablation.

83. The method of claim 75 wherein fastening the first area to the second area further comprises sliding a wedge disposed within an interior channel defined by the tissue adhering member such that the wedge urges a mechanical fastener to cinch the first area to the second area.

84. The method of claim 83 wherein the mechanical fastener is selected from the group consisting of C staples, U staples, clips, and tags.

85. The method of claim 75 further comprising disengaging the first area and the second area from the tissue adhering member.

86. The method of claim 75 wherein the organ comprises a stomach.

87. The method of claim 86 wherein the tissue adhering member is endoscopically inserted into the stomach via an esophageal passageway prior to releasably adhering a first area of the interior to a tissue adhering member.

88. The method of claim 75 wherein fastening the first area to the second area defines a boundary between the lumen and a remaining portion of the organ.

89. The method of claim 88 wherein the boundary is straight.

90. The method of claim 88 wherein the boundary approximates a curvature of the organ.

91. The method of claim 88 wherein the boundary is adjustable.

92. The method of claim 88 wherein the boundary flares towards the remaining portion of the organ.

93. The method of claim 75 wherein fastening the first area to the second area to form the lumen further comprises urging a fastener through an interior channel defined in the tissue adhering member to fasten the first area and the second area together.

94. The method of claim 93 wherein the fastener has a tapering helical shape with a piercing end.

95. The method of claim 93 wherein urging the fastener through the interior channel comprises rotating the fastener about a longitudinal axis defined by the fastener such that the first area and the second area cinches together.

96. A system for forming a lumen from an interior of an organ and for dilating an opening defined by the organ comprising:

a tissue adhering member having a proximal end and a distal end with a length therebetween, the member having at least two releasably adherable regions for releasably positioning a first area of the interior near a second area of the interior, whereby the lumen is formed upon fastening the first area to the second area; and,

an elongate device having a proximal end and a distal end with a length therebetween, the elongate device having a modifying region for contacting tissue in or around the opening and for delivering a stimulus to the tissue to dilate the opening.

97. The system of claim 96 further comprising at least one fastener disposable within the tissue adhering member for fastening the first area to the second area.

98. The system of claim 96 wherein the tissue adhering member defines a slot along the length.

99. The system of claim 98 wherein the slot is adapted to receive a retractable septum.

100. The system of claim 98 wherein the retractable septum defines at least one surface adapted to abrade an adjacent portion of the interior.

101. The system of claim 100 wherein the adjacent portion of the interior is abraded by the retractable septum using a method selected from the group consisting of cutting, scoring, heating, freezing, and chemical ablation.

102. The system of claim 96 wherein the first area and the second area are adhered to the tissue adhering member via a vacuum created in each of the two releasably adherable regions.

103. The system of claim 102 wherein each of the two releasably adherable regions are in fluid communication with a common channel defined within the tissue adhering member.

104. The system of claim 96 wherein the opening defined by the organ comprises a pylorus located at a distal end of the organ.

105. The system of claim 96 wherein the modifying region comprises a cutting member adapted to cut the tissue in or around the opening.

106. The system of claim 96 wherein the stimulus comprises a form of energy selected from the group consisting of heat energy, electrical energy, chemical energy, RF energy, and pressure.

107. The system of claim 96 wherein the elongate device comprises a dilatation device disposed near the distal end.

108. The system of claim 107 wherein the dilatation device comprises an angioplasty balloon.

109. The system of claim 96 wherein the elongate device comprises an angioplasty balloon disposed near the distal end, the balloon having the modifying region disposed on an exterior surface of the balloon.

110. The system of claim 109 wherein the modifying region comprises at least one cutting member disposed on the exterior surface.

111. The system of claim 110 wherein the cutting member is selected from the group consisting of blades and wires.

112. The system of claim 96 wherein the elongate device comprises a dilation wire basket disposed near the distal end, the dilation wire basket being adapted to deliver the stimulus to the tissue.

113. The system of claim 112 wherein the stimulus comprises a change in temperature.

114. The system of claim 96 wherein the modifying region comprises at least one probe extending from the distal end of the elongate device, the probe having a distal end adapted for piercing the tissue in or around the opening.

115. The system of claim 114 wherein the probe distal end is adapted to deliver a stimulus selected from the group consisting of heat energy, electrical energy, chemical energy, and RF energy.

116. The system of claim 96 wherein the stimulus comprises a chemical delivered through an opening defined in the modifying region.

117. The system of claim 116 wherein the chemical is ablative to the tissue in or around the opening.

118. The system of claim 117 wherein the chemical is selected from the group consisting of alcohol, sotrodecol, and Botox virus.

119. The system of claim 96 wherein the modifying region comprises a cutting wire extending between the elongate device distal end and a region proximal of the elongate device distal end.

120. The system of claim 96 wherein the modifying region is disposed at the distal end of the elongate device, the region defining a slot for receiving the tissue in or around the opening, and a cutting edge disposed between a plurality of staples slidingly held within the slot.

121. A method for forming a lumen from an interior of an organ and for dilating an opening defined by the organ comprising:

releasably adhering a first area of the interior to a tissue adhering member;

displacing the first area of the interior via the tissue adhering member;

releasably adhering a second area of the interior to the tissue adhering member such that the first area is positioned near the second area;

fastening the first area to the second area to form the lumen; and

dilating the opening defined at a distal end of the organ.

122. The method of claim 121 wherein the first area of the interior is releasably adhered to the tissue adhering member via a vacuum created in a first opening defined in the tissue adhering member.

123. The method of claim 121 wherein the second area of the interior is releasably adhered to the tissue adhering member via a vacuum created in a second opening defined in the tissue adhering member.

124. The method of claim 121 wherein releasably adhering a second area of the interior to the tissue adhering member such that the first area is positioned near the second area further comprises removing a septum disposed in the tissue adhering member such that the first area contacts the second area.

125. The method of claim 121 wherein the opening comprises a pyloral sphincter.

126. The method of claim 121 wherein dilating the opening comprises applying a stimulus to tissue in or around the opening via an elongated device having a proximal end and a distal end with a length therebetween.

127. The method of claim 126 wherein the stimulus comprises a form of energy selected from the group consisting of heat energy, electrical energy, chemical energy, RF energy, and pressure.

128. The method of claim 126 wherein the elongated device comprises a dilatation device disposed near the distal end.

129. The method of claim 128 wherein the dilatation device comprises an angioplasty balloon.

130. The method of claim 128 wherein the angioplasty balloon comprises an expandable surface having at least one cutting member disposed thereon.

131. The method of claim 121 wherein dilating the opening defined at the distal end of the organ comprises piercing tissue in or around the opening with at least one elongate probe and applying a stimulus via the elongate probe.

132. The method of claim 131 wherein the stimulus comprises a chemical delivered through an opening defined in a distal end of the probe.

133. The system of claim 132 wherein the chemical is ablative to the tissue in or around the opening.

134. The system of claim 133 wherein the chemical is selected from the group consisting of alcohol, sotrodecol, and Botox virus.

135. The method of claim 126 wherein the elongated device comprises a combination cutting edge and stapler disposed near the distal end.

136. A system for forming a lumen from an interior of an organ, comprising a rotatable device for insertion into the organ, the device being specially adapted to adhere onto an internal surface while being rotated about a longitudinal axis defined by the device.

137. The system of claim 136 further comprising a fastening device specially adapted to fasten a rotated portion of the organ to a remaining portion of the organ.

138. The system of claim 136 wherein the device is rotated at least about 180°.

139. The system of claim 136 wherein the device is rotated at least about 360°.

140. The system of claim 136 further comprising a side-to-side anastomosis device for coupling adjacent regions of digestive tract, the anastomosis device comprising a distal segment and a proximal segment, the distal and the proximal segments each being adapted to align in apposition with each other while maintaining the regions of digestive tract therebetween.

141. The system of claim 137 wherein the rotated portion is mechanically fastened to the remaining portion by a fastener selected from the group consisting of staples, blind staples, clips, tags, screws, and adhesives.

142. The system of claim 136 wherein the rotatable device for insertion is inserted into the organ endoscopically via an esophageal passageway.

143. The system of claim 140 wherein the anastomosis device is inserted into the digestive tract endoscopically via an esophageal passageway.

144. The system of claim 140 wherein the anastomosis device is inserted into the digestive tract laparoscopically.

145. The system of claim 136 wherein the rotatable device for insertion comprises an outer tube having a proximal end and a distal end with a lumen defined therebetween, the outer tube defining an opening proximal of the distal end.

146. The system of claim 145 wherein the internal surface within the organ is adhered to the device via a vacuum created in the opening.

147. The system of claim 145 wherein the distal end comprises an enclosed, tapered end.

148. The system of claim 145 wherein the rotatable device for insertion further comprises an inner tube having a proximal end and a distal end with a lumen defined therebetween, the inner tube defining an opening proximal of the distal end.

149. The system of claim 148 wherein the opening of the inner tube is configured to align with the opening of the outer tube.

150. The system of claim 149 wherein the inner tube is counter-rotatable about the longitudinal axis with the outer tube.

151. The system of claim 145 wherein the outer tube further comprises a plurality of attachment points disposed adjacent to the opening, the internal surface within the organ adhering to the outer tube via the attachment points.

152. The system of claim 151 wherein the attachment points are selected from the group consisting of tines, barbs, and hooks.

153. The system of claim 136 wherein the rotatable device for insertion comprises a split tube having at least two halves, each of the halves being separatable along a partition defined along the tube, the split tube comprising a proximal end and a distal end with a lumen defined therebetween, the split tube

further comprising a plurality of attachment points disposed on each half near the distal end.

154. The system of claim 153 wherein the attachment points are selected from the group consisting of tines, barbs, and hooks.

155. The system of claim 136 wherein the rotatable device for insertion comprises at least two adjacent tubes, each of the tubes having a proximal end and a distal end with a lumen defined therebetween, and each of the tubes defining an opening proximal of the distal end.

156. The system of claim 155 wherein each of the two adjacent tubes are adapted to counter-rotate.

157. The system of claim 155 wherein the internal surface within the organ is adhered to the device via a vacuum created in each of the openings.

158. The system of claim 136 wherein the rotatable device for insertion comprises at least one attachment tube and at least two compression members, the attachment tube being specially adapted to adhere to the internal surface within the organ, and the two compression members being adapted to compress a portion of the internal surface within the organ therebetween.

159. The system of claim 158 wherein the attachment tube defines an opening proximal of a distal end.

160. The system of claim 159 wherein the internal surface within the organ is adhered to the attachment tube via a vacuum created in the opening.

161. The system of claim 140 wherein the distal and the proximal segments are magnetically coupled together while maintaining the regions of digestive tract therebetween.

162. The system of claim 161 wherein the distal and the proximal segments are further coupled by mechanical fasteners.

163. The system of claim 162 wherein the mechanical fasteners are selected from the group consisting of grommet-type swages, snap lock fits, staples, screws, clips, and friction-fittings.

164. The system of claim 140 further comprising a deployment device comprising an elongate tubular member having a proximal end and a distal end with a lumen defined therebetween, the distal end being specially adapted to retain the proximal segment for alignment in apposition with the distal segment.

165. The system of claim 164 wherein the deployment device further comprises a coring ring in the distal end, the coring ring being adapted to pass through a center of the distal segment and the proximal segment for removal of the regions of digestive tract therebetween.

166. The system of claim 164 wherein the deployment device distal end is adapted to be manipulatable via the proximal end.

167. The system of claim 140 further comprising a locating device adapted to urge the distal segment into a predetermined location in the digestive tract.

168. The system of claim 167 wherein the locating device comprises a magnetized device selected from the group consisting of magnetic wands and magnetic pickups.

169. A side-to-side anastomosis device for coupling adjacent regions of digestive tract, the anastomosis device comprising:

a distal segment and a proximal segment, the distal and the proximal segments each being adapted to align in apposition with each other while maintaining the regions of digestive tract therebetween; and

a deployment device comprising an elongate tubular member having a proximal end and a distal end with a lumen defined therebetween, the distal end being specially adapted to retain the proximal segment for alignment in apposition with the distal segment.

170. The anastomosis device of claim 169 wherein the distal and the proximal segments are magnetically coupled together while maintaining the regions of digestive tract therebetween.

171. The anastomosis device of claim 170 wherein the distal and the proximal segments are further coupled by mechanical fasteners.

172. The anastomosis device of claim 171 wherein the mechanical fasteners are selected from the group consisting of grommet-type swages, snap lock fits, staples, screws, clips, and friction-fittings.

173. The anastomosis device of claim 169 wherein the deployment device further comprises a coring ring in the distal end, the coring ring being adapted to pass through a center of the distal segment and the proximal segment for removal of the regions of digestive tract therebetween.

174. The anastomosis device of claim 169 wherein the deployment device distal end is adapted to be manipulatable via the proximal end.

175. The anastomosis device of claim 169 further comprising a locating device adapted to urge the distal segment into a predetermined location in the digestive tract.

176. The anastomosis device of claim 175 wherein the locating device comprises a magnetized device selected from the group consisting of magnetic wands and magnetic pickups.

177. A system for organ volume reduction, comprising:

a device for insertion into an organ, the device being specially adapted to draw up a portion of an interior of the organ; and

a fastening device specially adapted to fasten the portion of interior.

178. The system of claim 177 further comprising a side-to-side anastomosis device for coupling adjacent regions of digestive tract, the anastomosis device comprising a distal segment and a proximal segment, the distal and the proximal segments each being adapted to align in apposition with each other while maintaining the regions of digestive tract therebetween.

179. The system of claim 177 wherein the device for insertion is inserted into the organ endoscopically via an esophageal passageway.

180. The system of claim 178 wherein the anastomosis device is inserted into the digestive tract endoscopically via an esophageal passageway.

181. The system of claim 178 wherein the anastomosis device is inserted into the digestive tract laparoscopically.

182. The system of claim 177 wherein the device for insertion comprises a tube having a proximal end and a distal end with a lumen defined therebetween, the lumen defining a passageway for drawing up the portion of the interior of the organ via a vacuum.

183. The system of claim 182 wherein the fastening device comprises an elastic band disposed about the distal end of the tube and adapted to slide over and secure the portion of the interior.

184. The system of claim 177 wherein the device for insertion comprises at least two elongate members, each member having a proximal end and a distal end with a length therebetween, the members being rotatably connected at the proximal end and the distal end such that the members are biased towards each other.

185. The system of claim 184 wherein the elongate members define an uneven surface.

186. The system of claim 177 wherein the device for insertion comprises an instrument having manipulatable grasping members at a distal end for grasping the portion of the interior of the organ.

187. The system of claim 186 wherein the fastening device comprises a catheter having a cinching distal end adapted to cinch the portion of the interior of the organ.

188. The system of claim 177 wherein the device for insertion comprises a tube having a proximal end and a distal end with a lumen defined therebetween, the distal end defining at least two slots.

189. The system of claim 188 wherein the slots are defined in apposition to each other.

190. The system of claim 188 wherein the device for insertion further comprises a plug adapted to fit into the distal end.

191. The system of claim 190 wherein the plug is biodegradable.

192. The system of claim 191 wherein the plug comprises a biodegradable polymer selected from the group consisting of polylactide, copolymers of polylactide, polyglycolide, and copolymers of polyglycolide.

193. The system of claim 177 wherein the fastening device comprises a clip adapted to be inserted into the lumen.

194. The system of claim 193 wherein the clip comprises two adjacent members attached at a proximal end, the distal ends of each member being configured to pierce tissue.

195. The system of claim 177 wherein the fastening device comprises a screw configured to be inserted into a channel defined within the device.

196. The system of claim 177 wherein the screw comprises a helical shape.

197. The system of claim 196 wherein a diameter of a distal end of the screw is larger than a diameter of a proximal end of the screw.

198. The system of claim 197 wherein a length between the distal end of the screw and the proximal end of the screw is tapered.

199. The system of claim 198 wherein the screw is configured to alternatingly pierce a first area of tissue and a second area of tissue while approximating the first area of tissue and the second area of tissue together.

200. The system of claim 177 further comprising a plurality of additional fastening devices, each of the fastening devices being configured to fasten the portion of interior while juxtaposed linearly to form a continuous fixation line.

201. A method of creating a side-to-side anastomosis in a digestive tract, comprising:

providing an anastomosis device comprising a distal segment and a proximal segment, the segments each being adapted to align in apposition with each other;

placing the distal segment into a section of digestive tract;

placing the proximal segment into a gastric pouch; and

aligning the distal segment with the proximal segment such that the segments are coupled together while maintaining a portion of the digestive tract and a portion of the gastric pouch therebetween.

202. The method of claim 201 wherein the distal segment and the proximal segment are aligned and coupled magnetically.

203. The method of claim 202 wherein the distal segment and the proximal segment are further coupled by mechanical fasteners.

204. The method of claim 203 wherein the mechanical fasteners are selected from the group consisting of grommet-type swages, snap lock fits, staples, screws, clips, and friction-fittings.

205. The method of claim 201 wherein the distal segment is placed into the section of digestive tract endoscopically via an esophageal passageway.

206. The method of claim 205 wherein the distal segment is placed into the section of digestive tract via a magnet located externally of the digestive tract.

207. The method of claim 201 wherein the distal segment is placed into the section of digestive tract laparoscopically.

208. The method of claim 201 wherein the proximal segment is placed into the gastric pouch endoscopically via an esophageal passageway.

209. The method of claim 201 further comprising advancing a coring device through a center of the proximal segment and the distal segment.

210. A method of creating a separate gastric lumen from a gastric pouch having a main lumen, comprising:

adhering a portion of interior of the gastric pouch to a device specially adapted to rotate;

rotating the device about a longitudinal axis defined by the device while maintaining adherence to the portion of interior, the device being rotated until the separate gastric lumen is defined; and

fastening the portion of interior to the gastric pouch such that the gastric lumen is maintained.

211. The method of claim 210 wherein the device comprises a tube having a proximal end and a distal end with a lumen defined therebetween, the tube defining an opening proximal of the distal end.

212. The method of claim 211 wherein the portion of interior is adhered to the device via a vacuum created in the opening.

213. The method of claim 211 wherein the portion of interior is adhered to the device via a plurality of attachment points disposed adjacent to the opening.

214. The method of claim 213 wherein the attachment points are selected from the group consisting of tines, barbs, and hooks.

215. The method of claim 210 wherein the portion of interior is fastened to the gastric pouch by a mechanical fastener selected from the group consisting of staples, blind staples, clips, tags, screws, and adhesives.

216. A method for gastric reduction, comprising:

creating a first side-to-side anastomosis between a first portion of digestive tract and a gastric pouch using the anastomosis device as described in claim 169;

creating a second side-to-side anastomosis between a second portion of digestive tract and a third portion of digestive tract using the anastomosis device as described in claim 169; and

creating a separate gastric lumen from the gastric pouch using the system as described in claim 136.

217. The method of claim 216 wherein the first portion of digestive tract comprises a predetermined section selected from the group consisting of duodenum and jejunum.

218. The method of claim 216 wherein the second portion of digestive tract comprises a predetermined section of duodenum.

219. The method of claim 216 wherein the third portion of digestive tract comprises a predetermined section of ileum.

220. The method of claim 216 wherein creating a second side-to-side anastomosis further comprises closing off a section of digestive tract disposed intermediate of the first portion and the second portion.

221. The method of claim 220 wherein the section of digestive tract disposed intermediate of the first portion and the second portion comprises duodenum.

222. The method of claim 216 wherein the first anastomosis is located about 20 to 50 cm from a pylorus of the gastric pouch.

223. The method of claim 216 wherein the second anastomosis is located about 15 to 55 cm from the pylorus of the gastric pouch.

224. The method of claim 216 wherein the second anastomosis is located about 150 to 200 cm along the digestive tract from the pylorus of the gastric pouch.

225. A modified gastric pouch, comprising:

a gastric pouch having an exterior surface and an interior surface defining a main lumen and a proximal gastric pouch opening proximal of the main lumen; and

a gastric lumen having a proximal end and a distal end and an interior surface between these ends formed from a rotated portion of the interior surface of the gastric pouch such that the gastric lumen defines a volume separate from the main lumen, the gastric lumen remaining in communication with an esophagus.

226. The modified gastric pouch of claim 225 further comprising a plurality of fasteners attached to an interface defined by the gastric lumen and the gastric pouch.

227. The modified gastric pouch of claim 226 wherein the fasteners comprise biocompatible mechanical fasteners selected from the group consisting of staples, tags, clips, sutures, screws, and adhesives.

228. The modified gastric pouch of claim 225 wherein the gastric lumen is straight.

229. The modified gastric pouch of claim 225 wherein the gastric lumen is tapered such that the distal end is larger than the proximal end.

230. The modified gastric pouch of claim 225 wherein the gastric lumen is tapered such that the proximal end is larger than the distal end.

231. The modified gastric pouch of claim 225 wherein the gastric lumen proximal end defines a gastric lumen proximal opening and the gastric lumen proximal end and the gastric lumen proximal opening are coaxially located.

232. An overtube system for insertion into a body, comprising:

an elongate overtube having a proximal end, a distal end, and a length therebetween, wherein the overtube defines at least one opening near or at the distal end of the overtube and wherein the opening is adapted to adhere tissue thereto;

a tubular member adjustably disposed within a first lumen defined within the overtube, wherein the tubular member defines a second lumen therethrough; and

a fastening assembly disposed within the first lumen and adapted to fasten the tissue adhered to the opening.

233. The system of claim 232 wherein the overtube defines at least two openings near or at the distal end of the overtube in apposition with one another.

234. The system of claim 233 wherein the openings are slots longitudinally defined along the length of the overtube.

235. The system of claim 233 wherein the overtube further comprises a wall extending longitudinally within the overtube at least partially and which separates the first lumen between the two openings.

236. The system of claim 232 wherein the overtube defines a plurality of openings near the distal end, wherein each of the openings are defined in an alternating and apposing pattern between adjacent openings.

237. The system of claim 232 wherein the overtube distal end is in fluid communication with the proximal end through the first lumen.

238. The system of claim 232 wherein the elongate overtube is adapted to conform to an arbitrary configuration when in a relaxed state and to selectively maintain the arbitrary configuration when in a rigidized state.

239. The system of claim 238 wherein the elongate overtube further comprises at least one tensioning member disposed throughout the length of the

overtube, the tensioning member being manipulatable at its proximal end whereby applying a tensile force to the member causes the overtube to rigidize and relaxing the member causes the overtube to become flexible.

240. The system of claim 232 wherein a distal end portion of the elongate overtube is adapted to be manipulatable via a controller located proximally of and in communication with the distal end portion.

241. The system of claim 232 wherein the tubular member is disposed within the overtube such that the tubular member is rotatable about a longitudinal axis defined by the tubular member.

242. The system of claim 232 wherein the second lumen of the tubular member is adapted to slidingly receive an endoscope shaft.

243. The system of claim 232 wherein the proximal end of the overtube comprises a fluid port in communication with the distal end of the overtube via the first lumen.

244. The system of claim 232 wherein the proximal end of the overtube comprises an entry port through which the tubular member is disposed, wherein the entry port is adapted to form a fluid-tight seal with an outer surface of the tubular member.

245. The system of claim 232 wherein the fastening assembly comprises a fastener having a helically shaped elongate member having a tapered distal end.

246. The system of claim 245 wherein the fastener is disposed distally of the tubular member, wherein a distal end of the tubular member is adapted to engage and distally advance the fastener.

247. The system of claim 245 wherein the distal end of the tubular member comprises an engagement surface adapted to engage a proximal end of

the fastener, wherein rotating the tubular member about its longitudinal axis rotates and distally advances the fastener.

248. The system of claim 232 wherein the fastening assembly comprises an elongated shaft having a proximal end and a distal end with a stapling device attached thereto.

249. The system of claim 232 wherein the fastening assembly comprises a staple.

250. The system of claim 232 wherein the fastening assembly comprises an elongate member having a tapered distal end.

251. The system of claim 232 further comprising a guard member slidably disposed along the length of the overtube, wherein the guard member is adapted for placement about an opening into the body for providing structural support to the overtube.

252. The system of claim 232 wherein the overtube comprises at least one mark defined on an outer surface near or at the proximal end of the overtube, wherein the mark corresponds to a circumferential position of the opening near or at the distal end of the overtube.

253. The system of claim 232 further comprising a mandrel insertable within the length of the overtube for defining a shape of the distal end of the overtube.

254. The system of claim 253 wherein the mandrel has a straight configuration and constrains the overtube into a straightened configuration when inserted within the length of the overtube.

255. The system of claim 253 wherein the mandrel has a distal end which defines a curved shape.

256. An overtube system for insertion into a body, comprising:

an elongate overtube having a proximal end, a distal end, and a length therebetween, wherein the overtube defines at least one opening near or at the distal end of the overtube and wherein the opening is adapted to adhere tissue thereto;

a tubular member adjustably disposed within a first lumen defined within the overtube, wherein the tubular member defines a second lumen therethrough;

a fastening assembly disposed within the first lumen and adapted to fasten the tissue adhered to the opening; and,

a pump in fluid communication with the first lumen of the overtube.

257. The system of claim 256 wherein the pump is connected to the overtube via a fluid port defined near or at the proximal end of the overtube.

258. The system of claim 256 wherein the pump comprises a negative pressure pump.

259. The system of claim 256 wherein the pump comprises a positive pressure pump.

260. The system of claim 256 wherein the proximal end of the overtube comprises an entry port through which the tubular member is disposed, wherein the entry port is adapted to form a fluid-tight seal with an outer surface of the tubular member.

261. The system of claim 256 further comprising an endoscope for insertion into the second lumen of the tubular member.

262. An overtube system for insertion into a body, comprising:

an elongate overtube having a proximal end, a distal end, and a length therebetween, wherein the overtube defines at least a first and a second opening in apposition with one another near or at the distal end of the overtube, wherein the openings are separated from one another by a wall at least partially extending longitudinally within the overtube such that a first and a second lumen are defined within the overtube, and wherein the openings are adapted to adhere tissue thereto;

a tubular member adjustably disposed proximally of the wall within the overtube, wherein the tubular member defines an inner lumen therethrough; and

a fastening assembly disposed within the inner lumen and adapted to fasten the tissue adhered to the openings.

263. The system of claim 262 wherein the first opening is in fluid communication with the first lumen and the second opening is in fluid communication with the second lumen.

264. The system of claim 262 wherein the openings are slots longitudinally defined along the length of the overtube.

265. A method of treating a hollow body organ from within the hollow body organ comprising:

advancing a distal end of an overtube within the hollow body organ, the overtube defining at least one opening near or at the distal end and wherein the opening is adapted to adhere tissue from the hollow body organ thereto;

drawing apposed regions from the tissue of interest within the at least one opening;

distally advancing a tubular member through a lumen defined within the overtube such that a fastening assembly disposed within the lumen and engaged to a distal end of the tubular member is advanced distally; and

engaging the apposed regions of tissue within the lumen with the fastener.

266. The method of claim 265 wherein advancing the distal end of the overtube comprises advancing the overtube in a relaxed state to conform to an arbitrary configuration and further rigidizing the overtube to maintain the arbitrary configuration.

267. The method of claim 266 wherein the arbitrary configuration is defined by a controllable distal end portion of an endoscope inserted within the overtube.

268. The method of claim 266 wherein rigidizing the overtube comprises applying a tensile force to a tensioning member disposed within the overtube.

269. The method of claim 265 wherein drawing apposed regions from the tissue of interest comprises drawing the tissue within the opening via a vacuum force.

270. The method of claim 269 wherein the tissue is drawn from at least two apposed regions.

271. The method of claim 269 wherein the tissue is drawn from alternating and apposed regions.

272. The method of claim 265 further comprising advancing an endoscope distally through the lumen defined within the overtube to identify at least one region of tissue of interest prior to drawing the apposed regions from the tissue of interest.

273. The method of claim 272 wherein advancing the endoscope distally comprises advancing a distal end of the endoscope beyond the distal end of the overtube.

274. The method of claim 272 further comprising withdrawing the endoscope proximally into the lumen prior to distally advancing the tubular member.

275. The method of claim 272 wherein the tubular member is advanced distally over the endoscope disposed within the lumen.

276. The method of claim 265 wherein distally advancing the tubular member comprises advancing the tubular member longitudinally.

277. The method of claim 276 wherein distally advancing the tubular member further comprises rotating the tubular member about a longitudinal axis defined by the tubular member.

278. The method of claim 265 wherein engaging the apposed regions of tissue further comprises approximating the tissue with the fastener.

279. The method of claim 265 wherein engaging the apposed regions of tissue comprises piercing the tissue with the fastener.

280. The method of claim 265 further comprising orienting the overtube relative to the hollow body organ by aligning at least one mark defined on the overtube with a landmark located externally of the hollow body organ prior to drawing the apposed regions from the tissue of interest.

281. The method of claim 265 wherein engaging the apposed regions of tissue comprises clamping the tissue with the fastening assembly while engaging the tissue with the fastener.

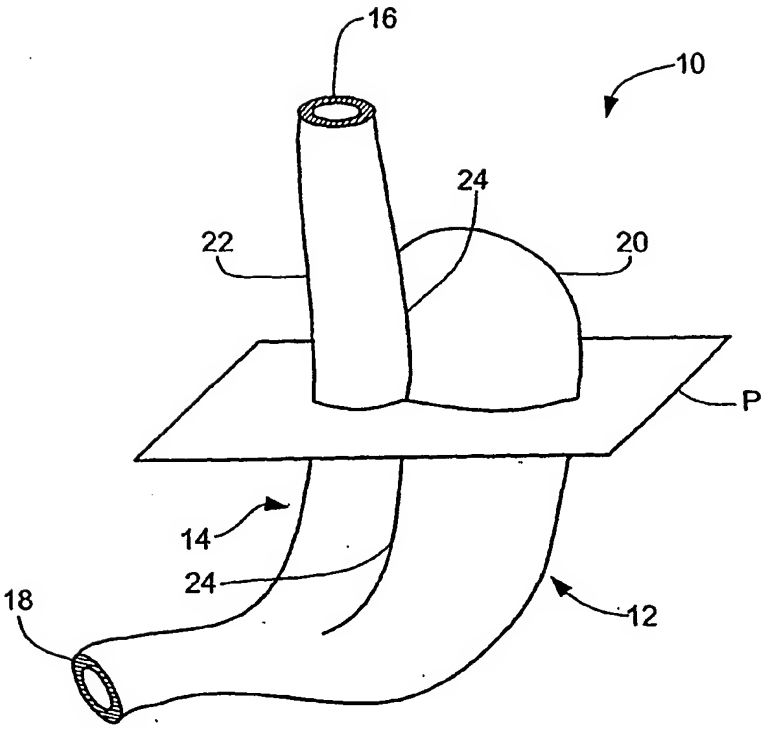

FIG. 1A

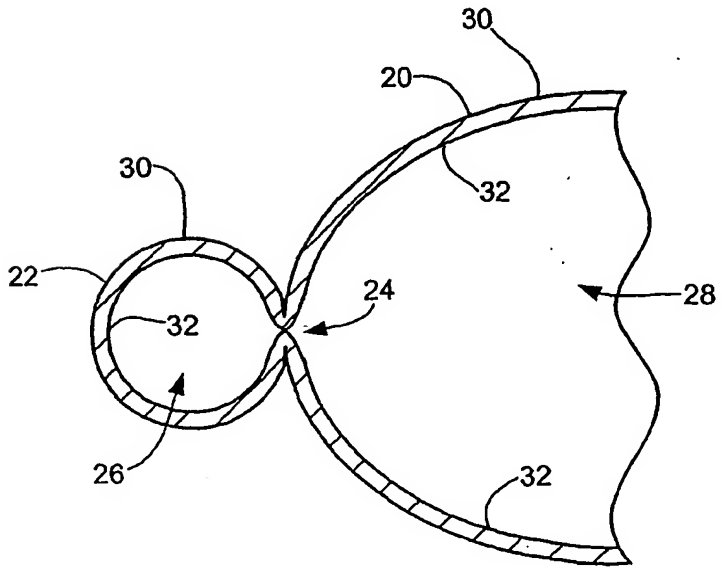

FIG. 1B

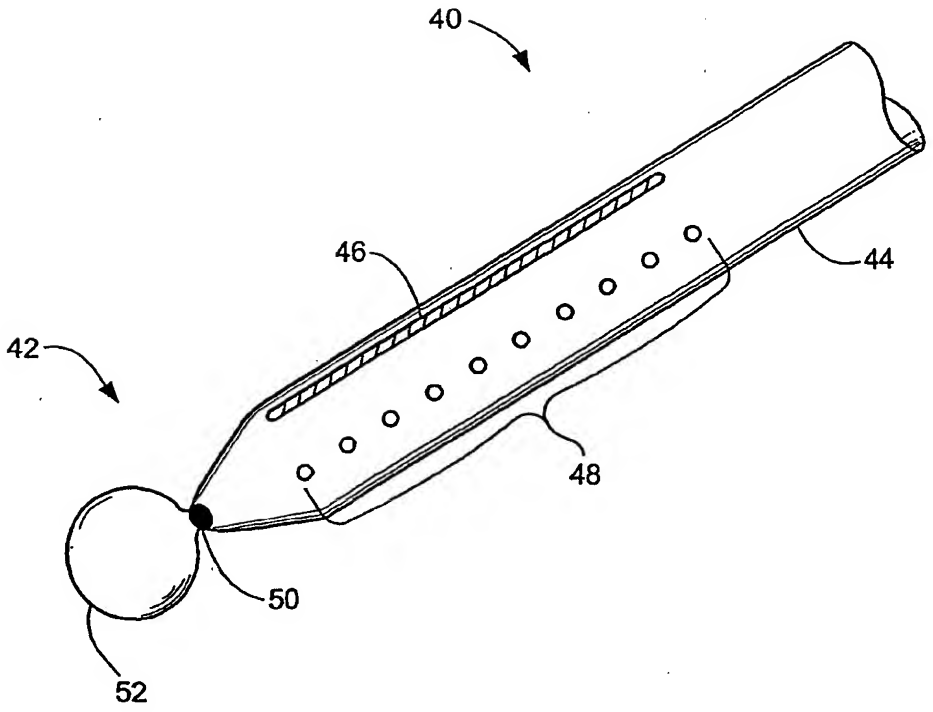

FIG. 2

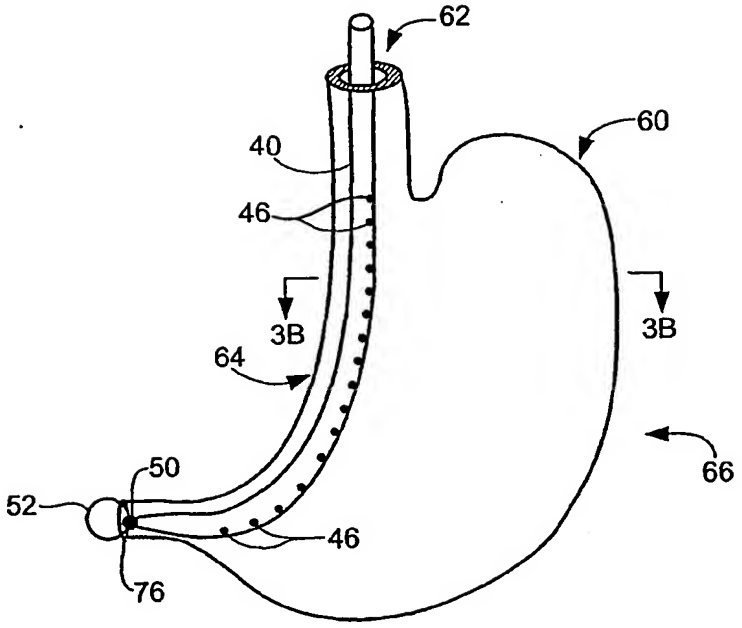

FIG. 3A

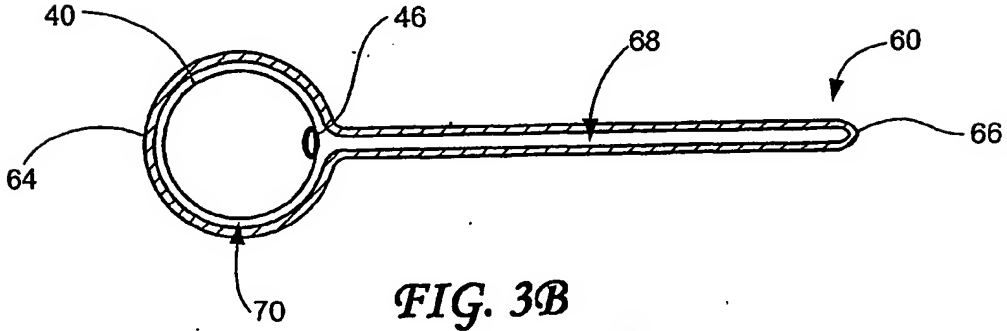

FIG. 3B

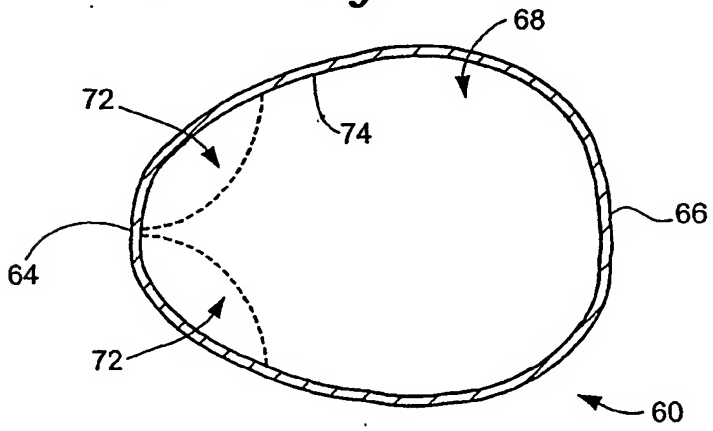

FIG. 3C

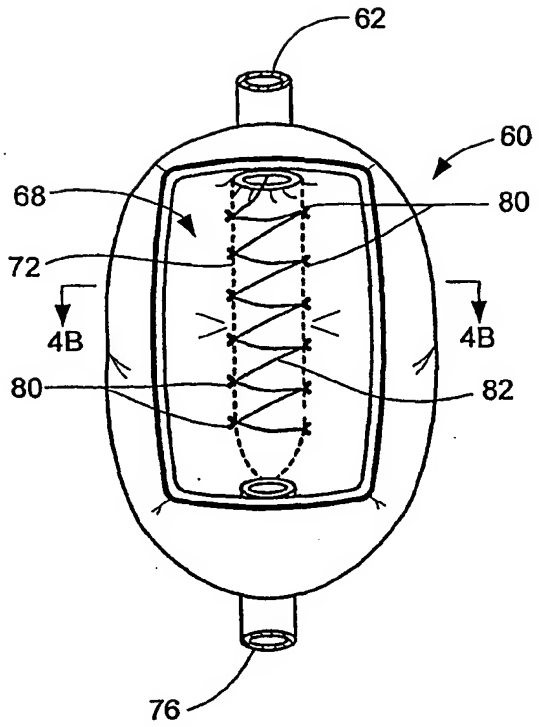

FIG. 4A

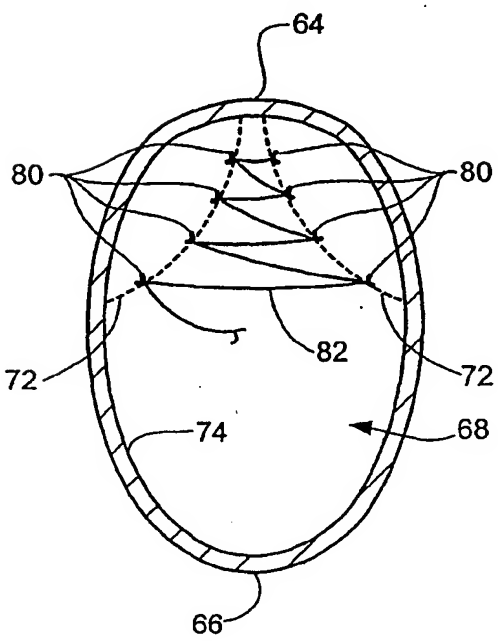

FIG. 4B

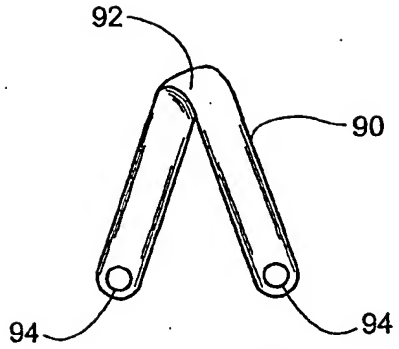

FIG. 5A

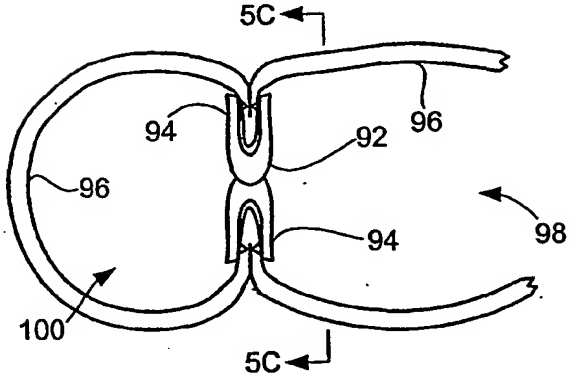

FIG. 5B

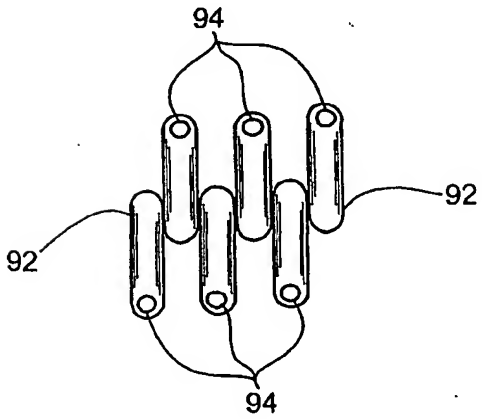

FIG. 5C

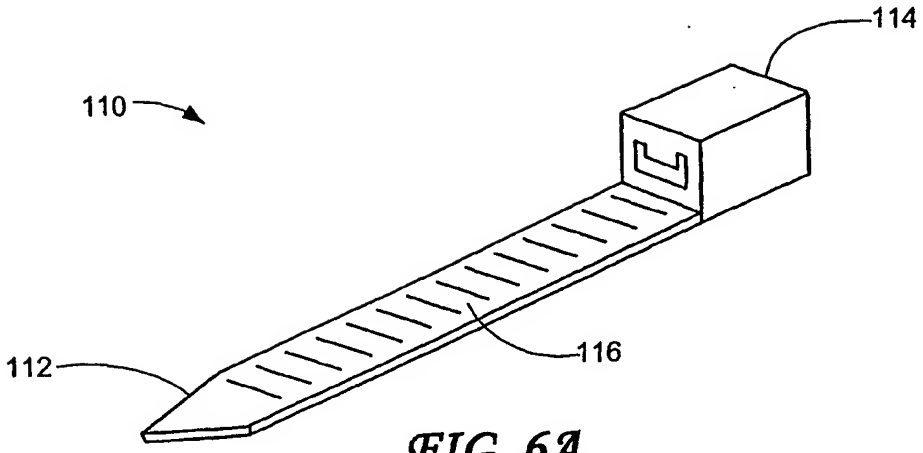

FIG. 6A

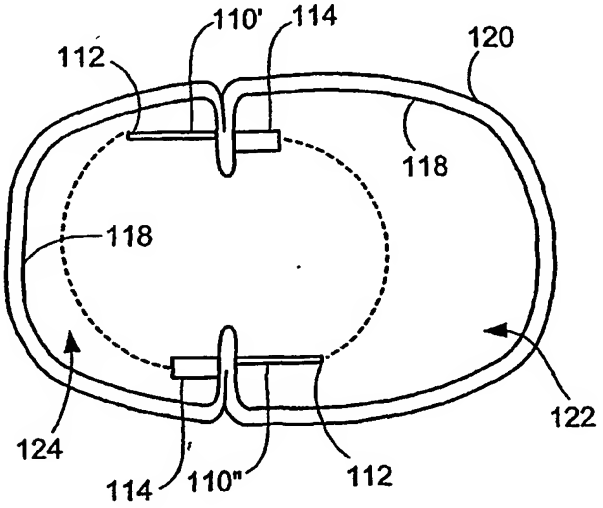

FIG. 6B

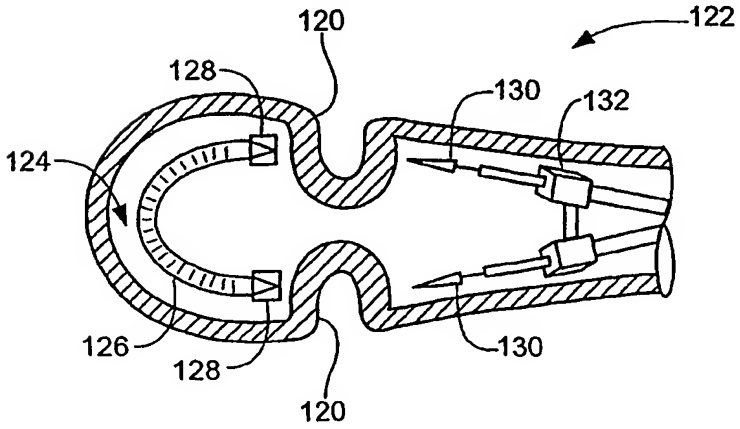

FIG. 6C

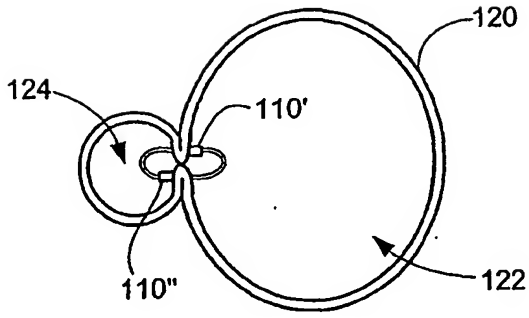

FIG. 6D

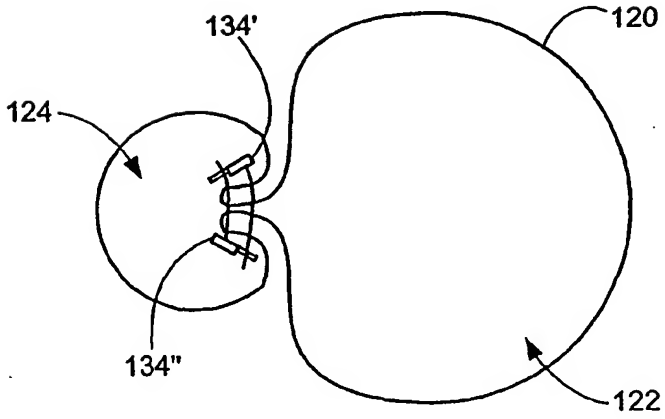

FIG. 6E

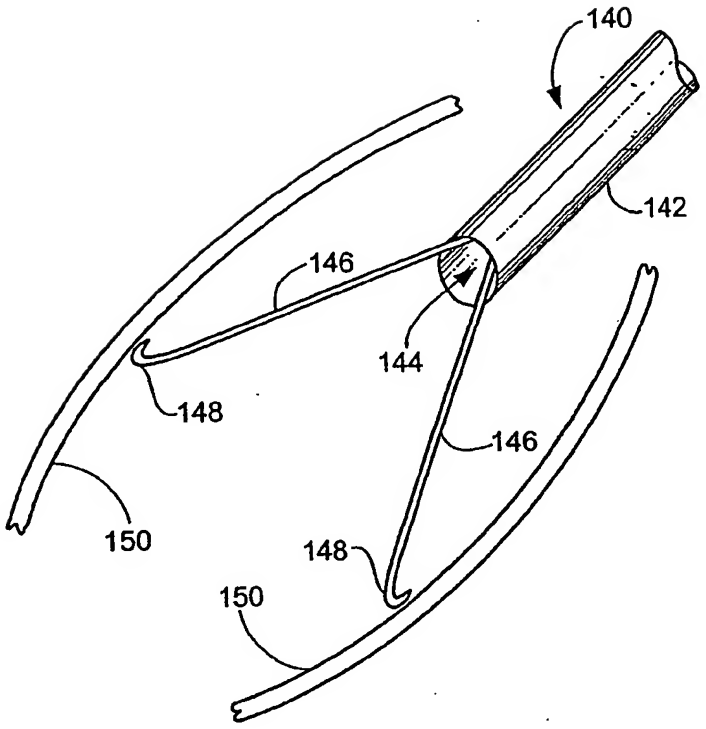

FIG. 7A

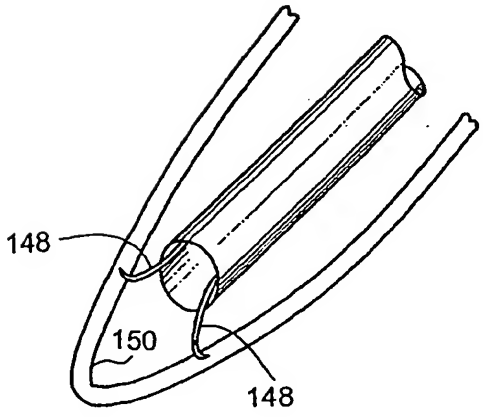

FIG. 7B

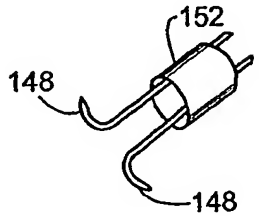

FIG. 7C

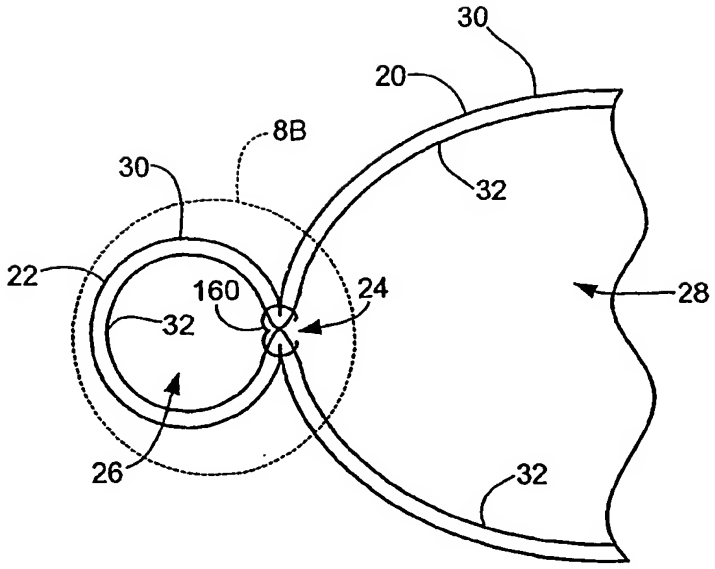

FIG. 8A

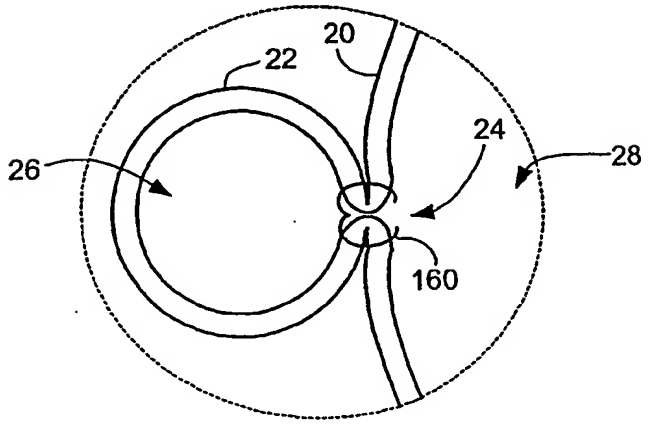

FIG. 8B

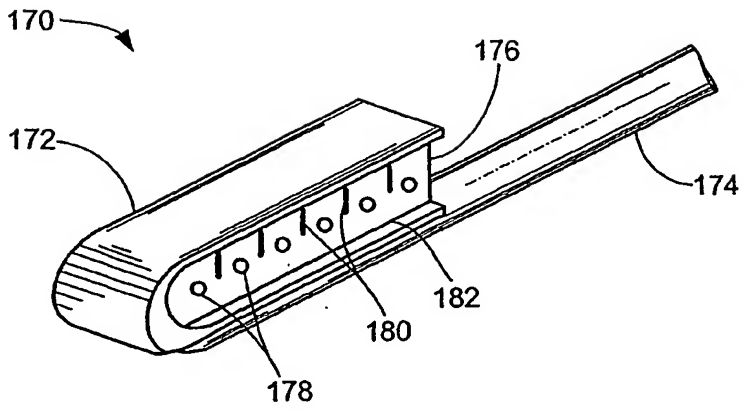

FIG. 9A

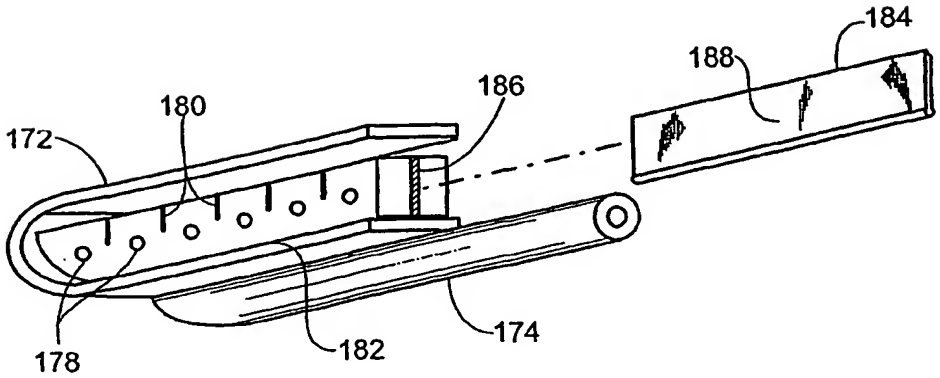

FIG. 9B

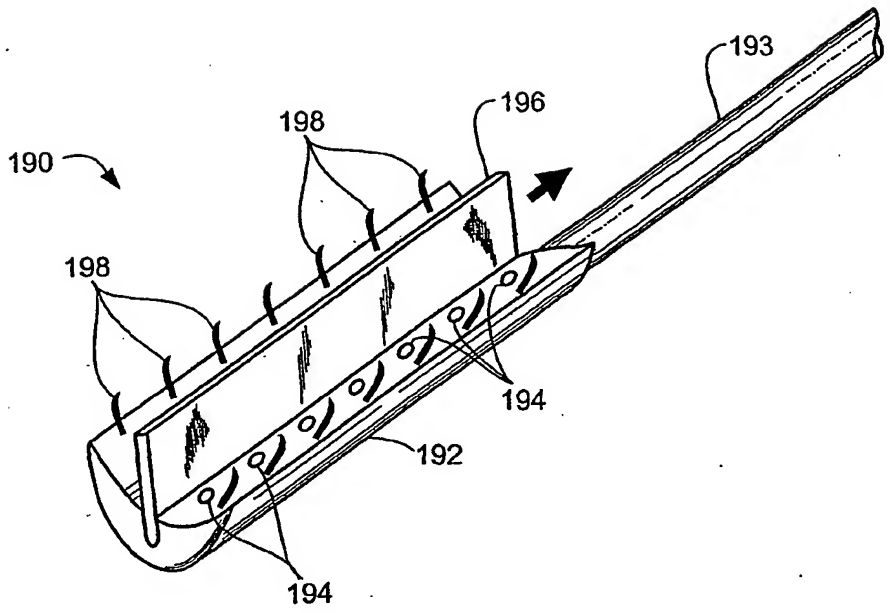

FIG. 10

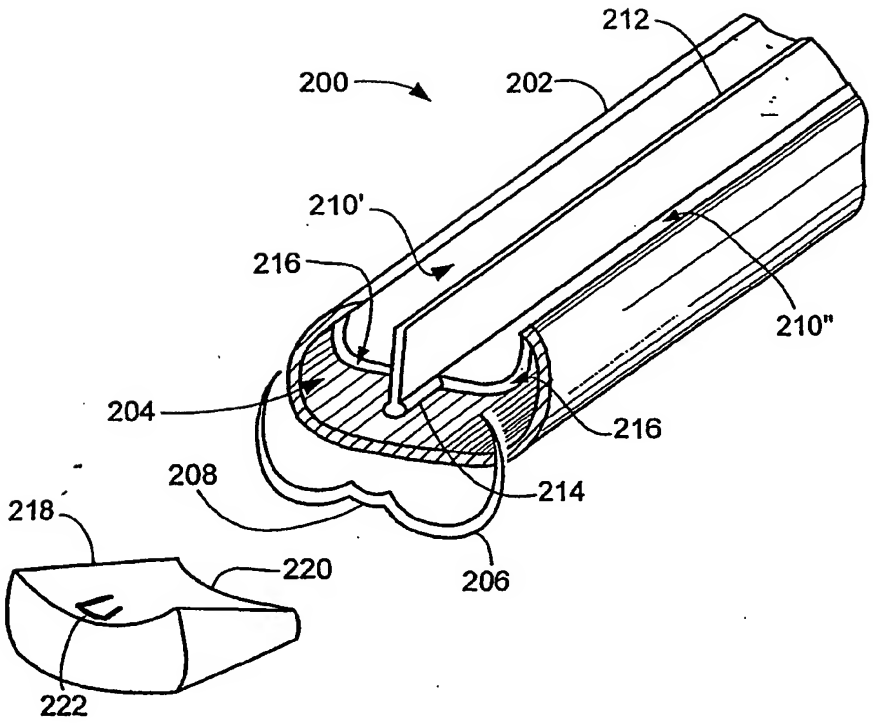

FIG. 11A

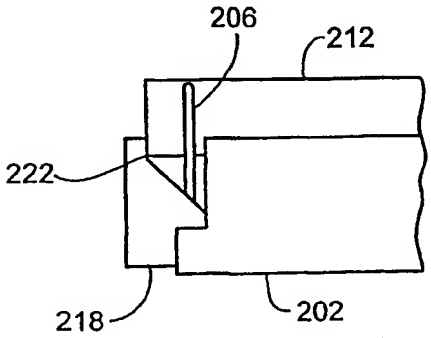

FIG. 11B

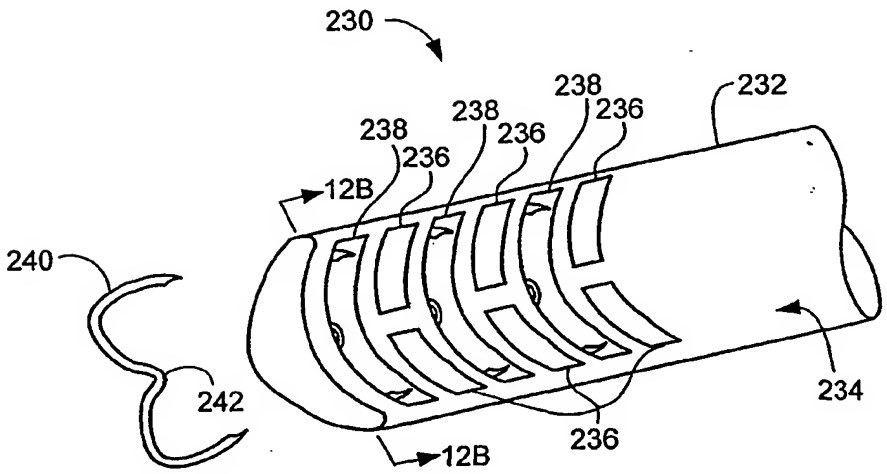

FIG. 12A

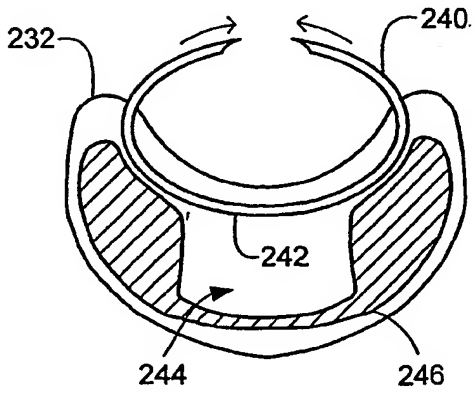

FIG. 12B

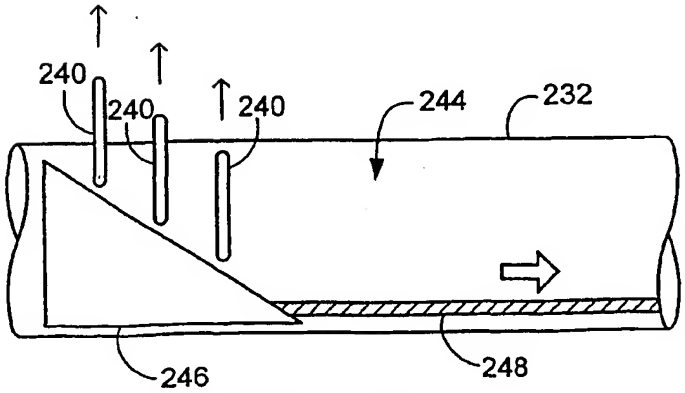

FIG. 12C

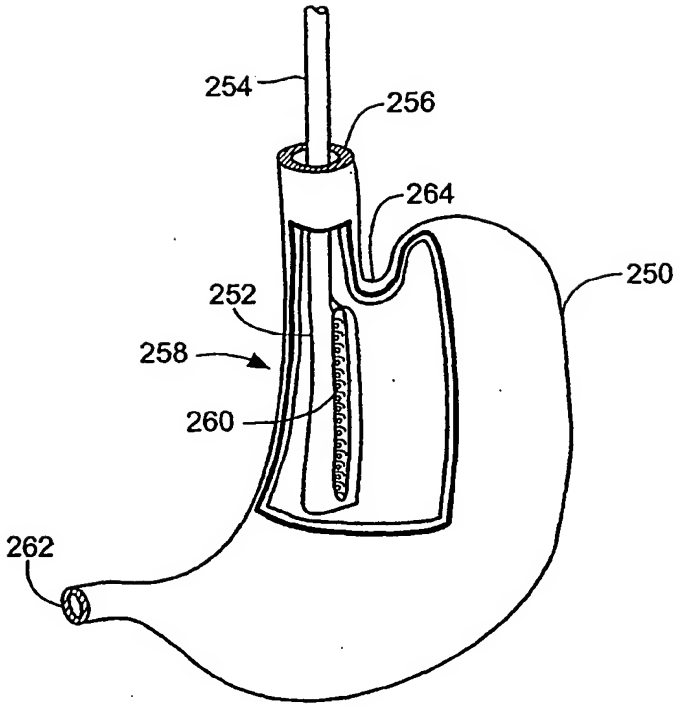

FIG. 13

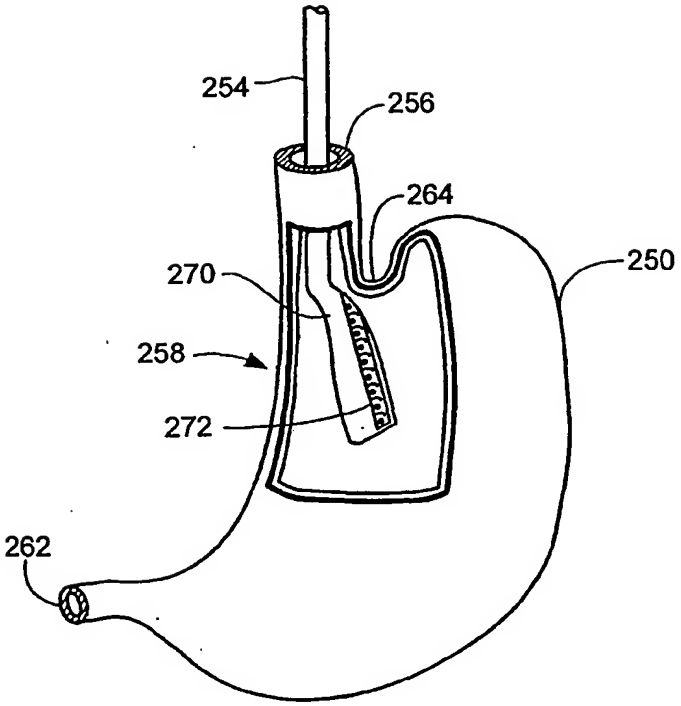

FIG. 14

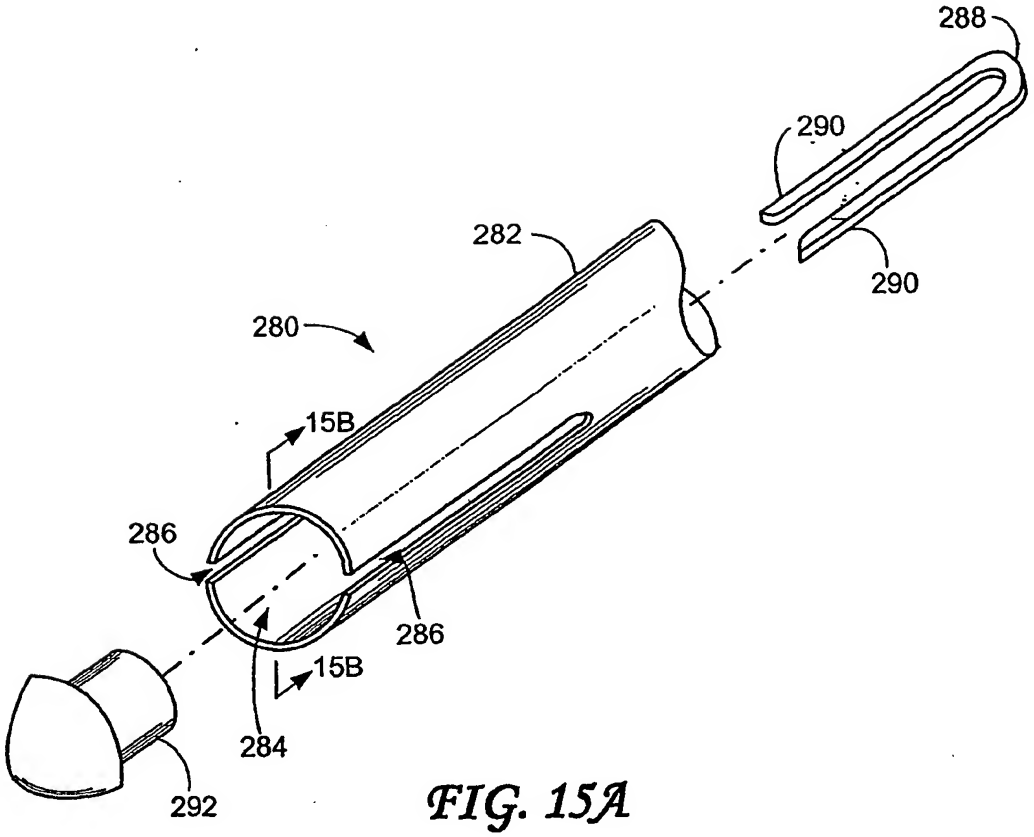

FIG. 15A

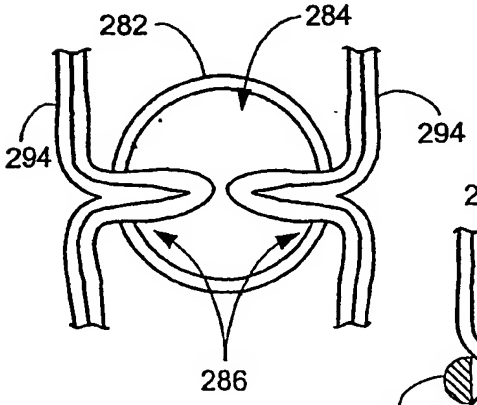

FIG. 15B

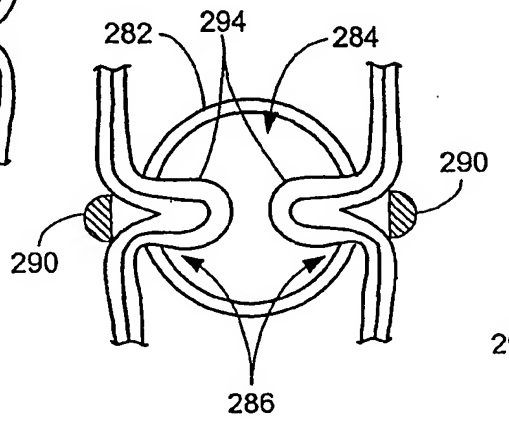

FIG. 15C

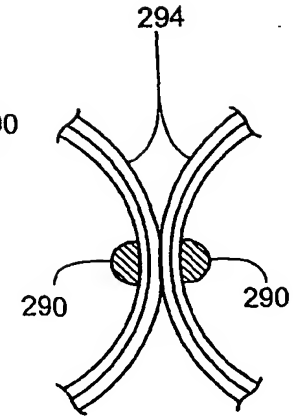

FIG. 15D

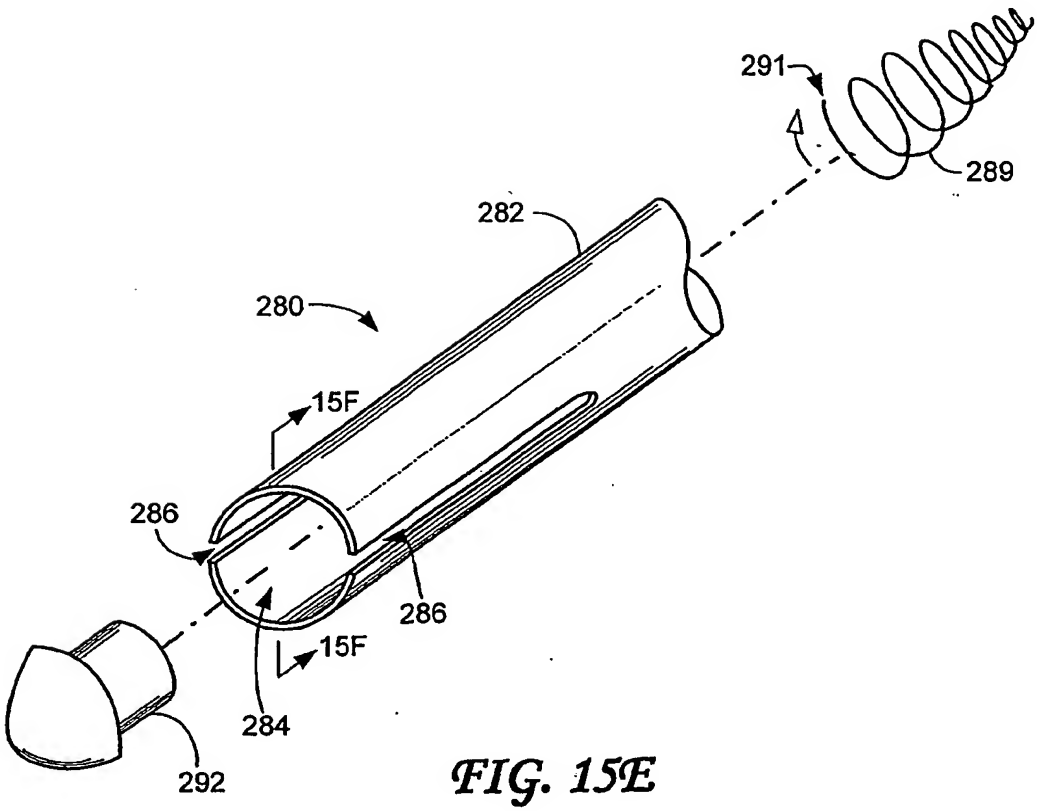

FIG. 15E

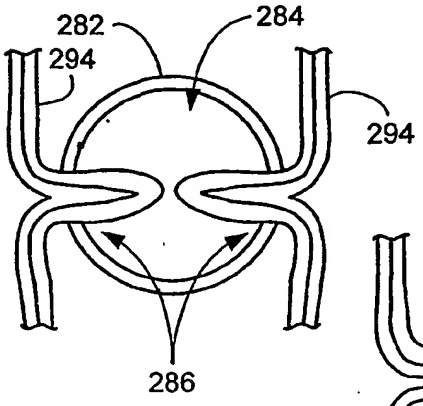

FIG. 15F

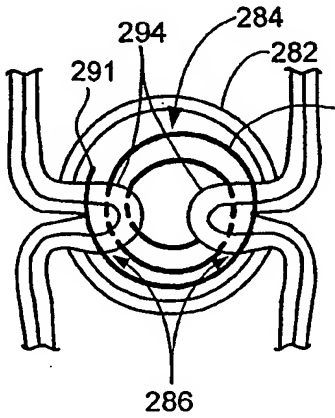

FIG. 15G

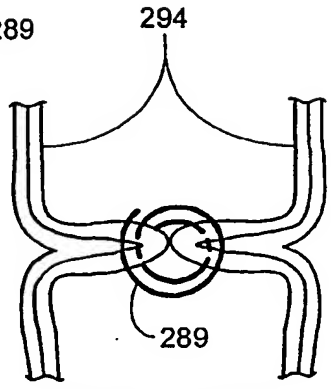

FIG. 15H

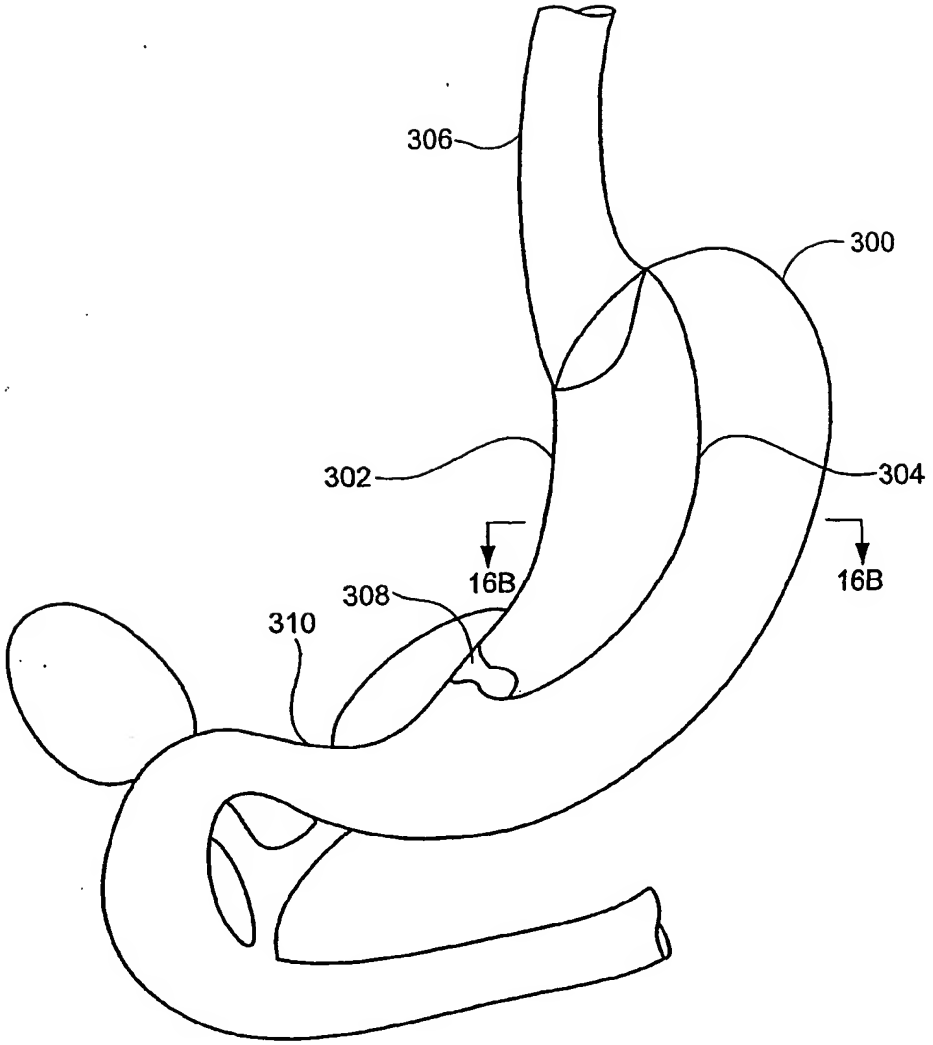

FIG. 16A

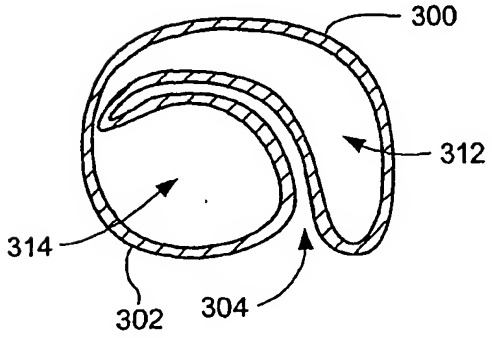

FIG. 16B

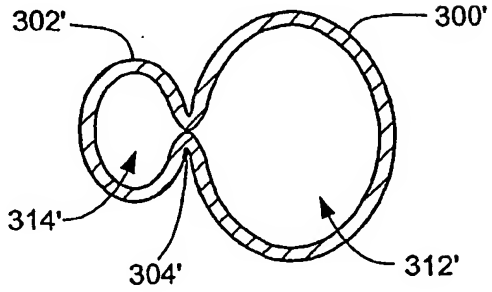

FIG. 16C

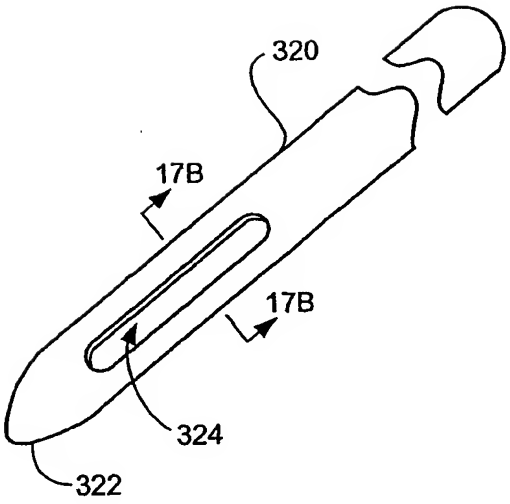

FIG. 17A

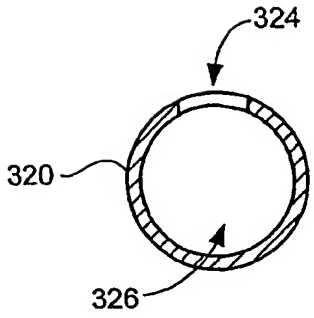

FIG. 17B

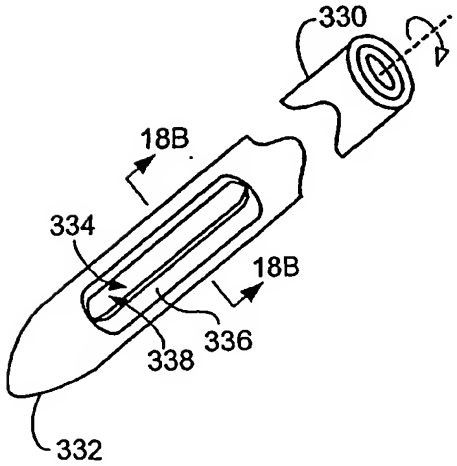

FIG. 18A

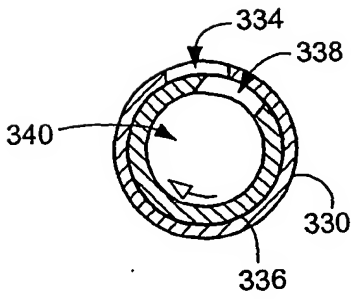

FIG. 18B

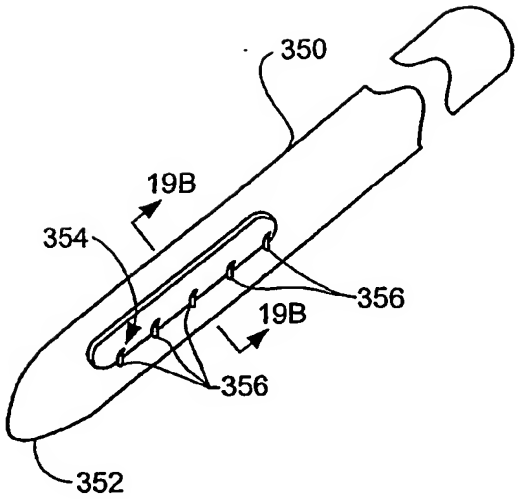

FIG. 19A

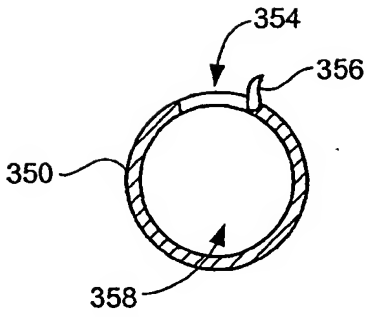

FIG. 19B

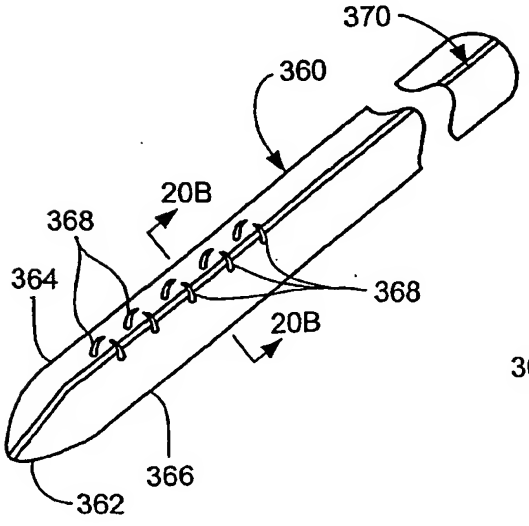

FIG. 20A

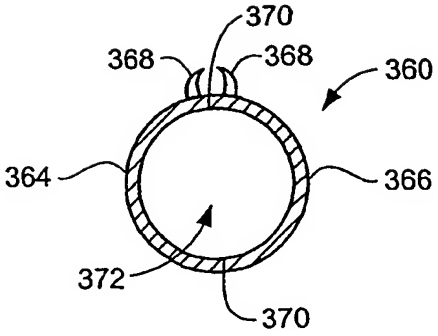

FIG. 20B

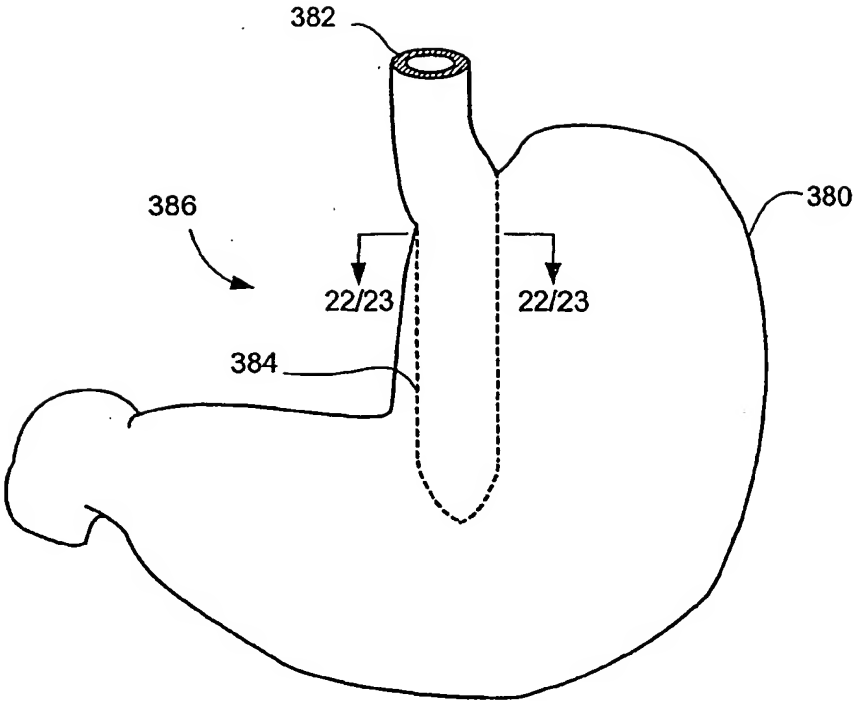

FIG. 21

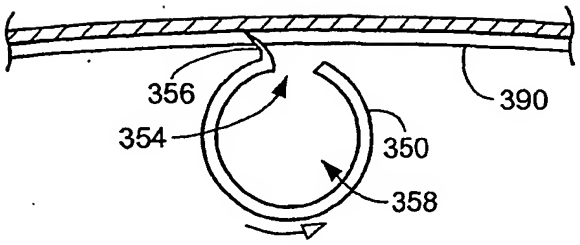

FIG. 22A

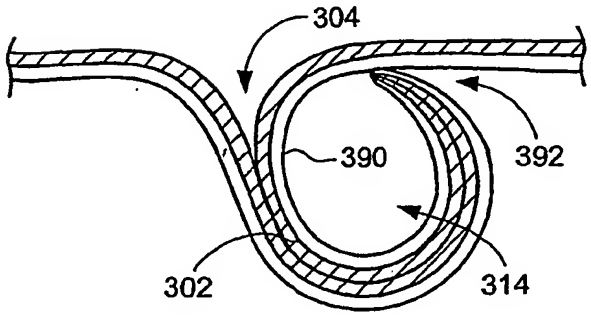

FIG. 22B

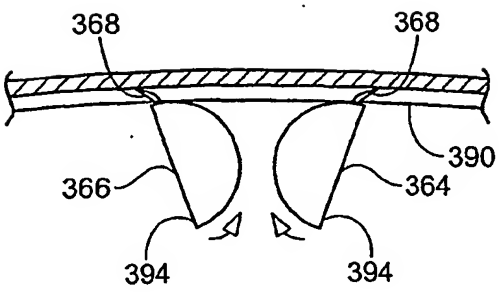

FIG. 23A

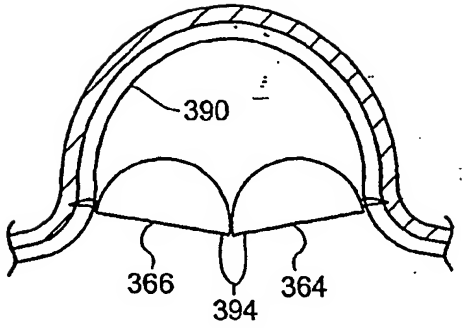

FIG. 23B

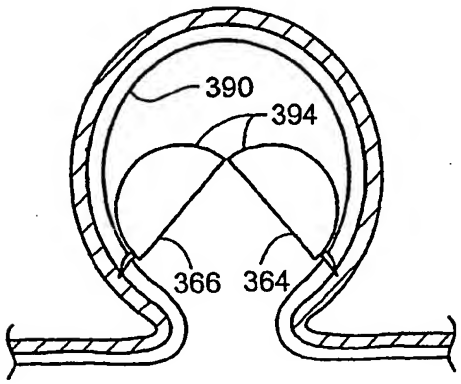

FIG. 23C

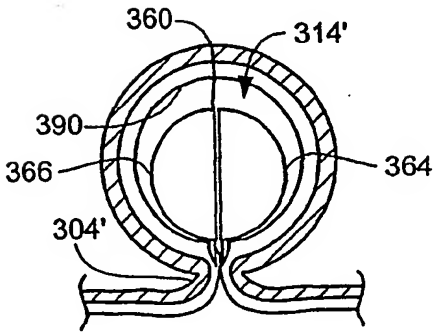

FIG. 23D

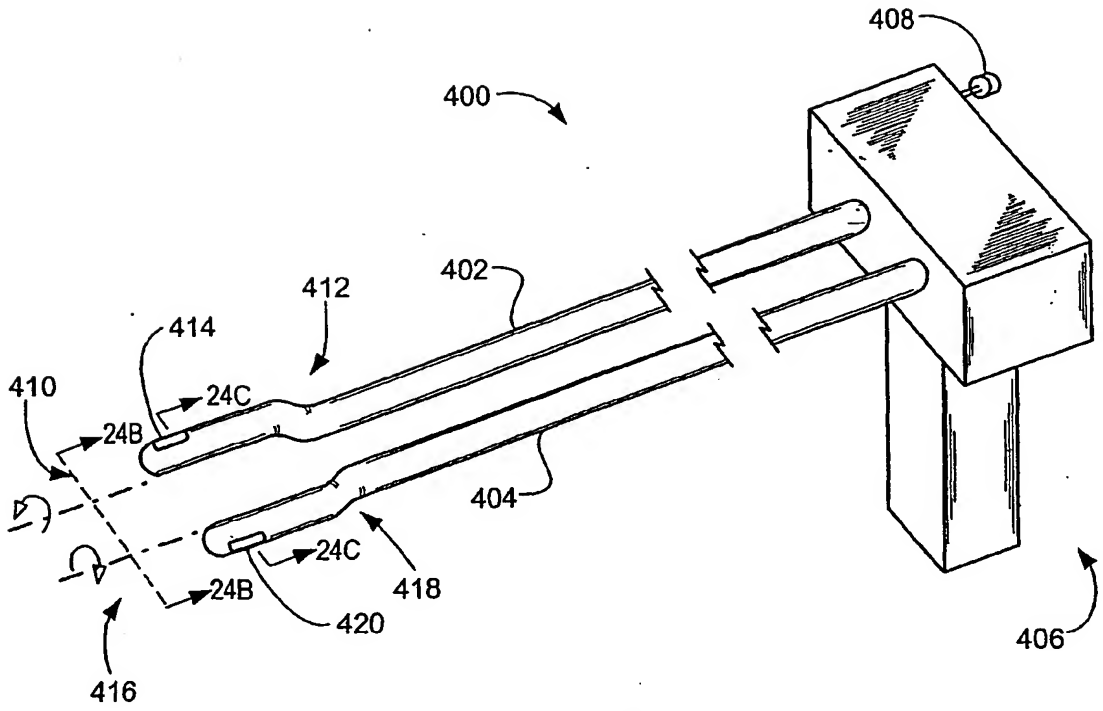

FIG. 24A

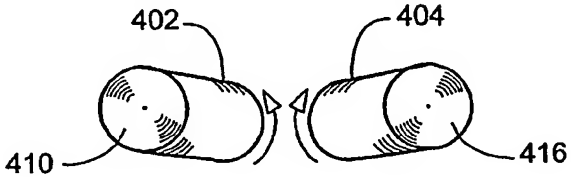

FIG. 24B

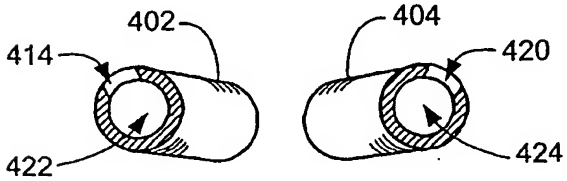

FIG. 24C

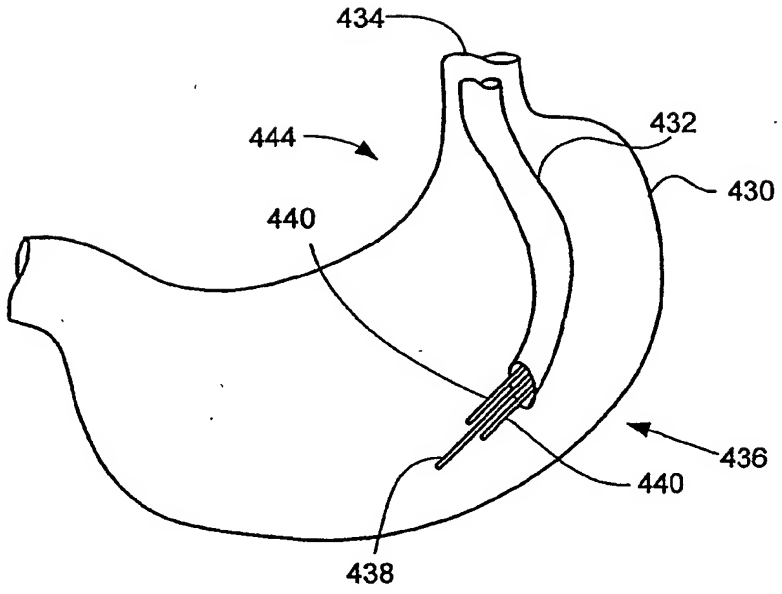

FIG. 25A

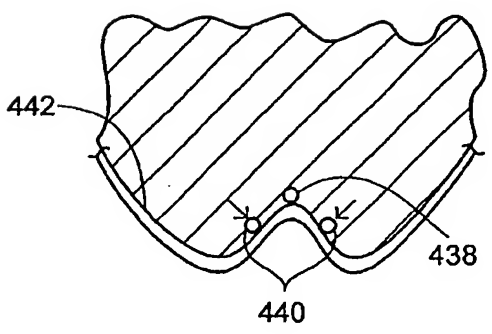

FIG. 25B

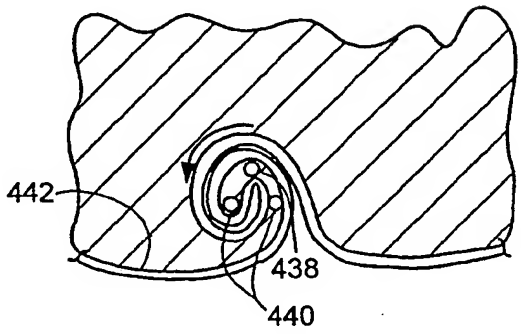

FIG. 25C

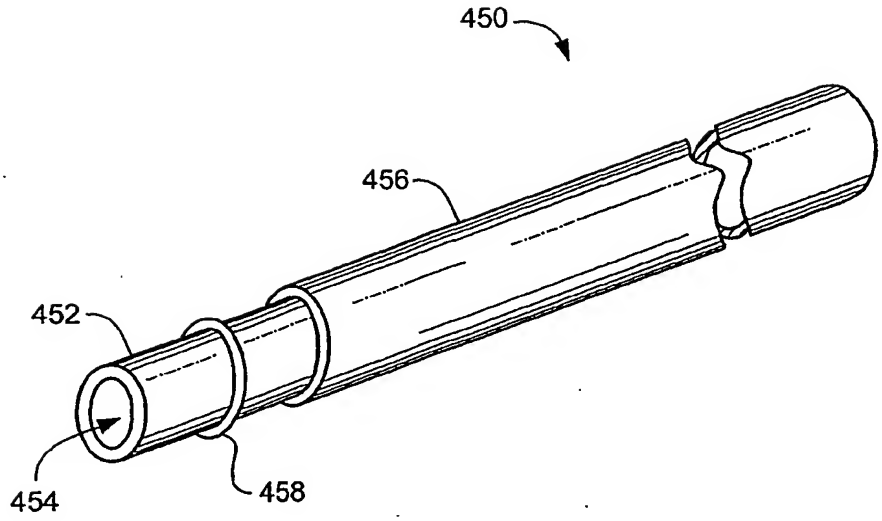

FIG. 26

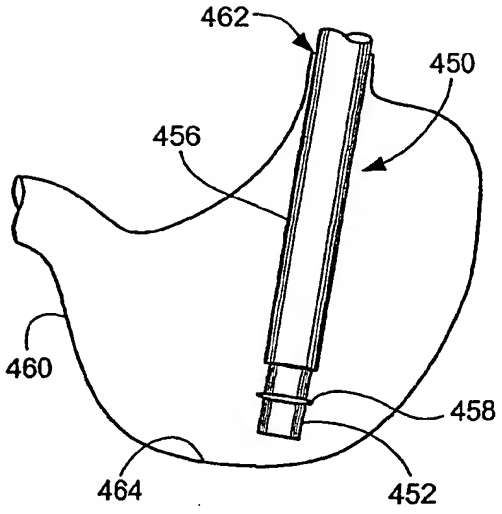

FIG. 27A

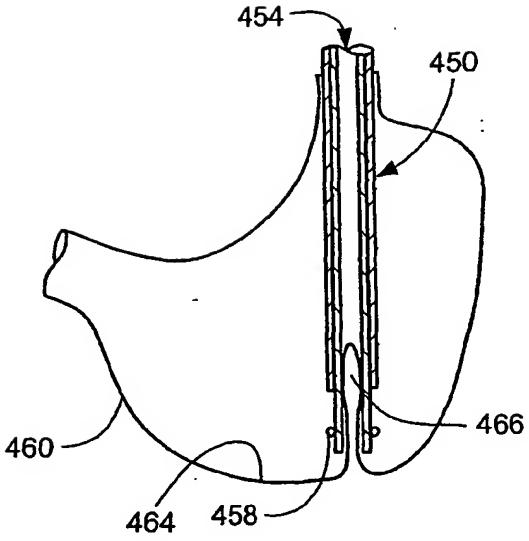

FIG. 27B

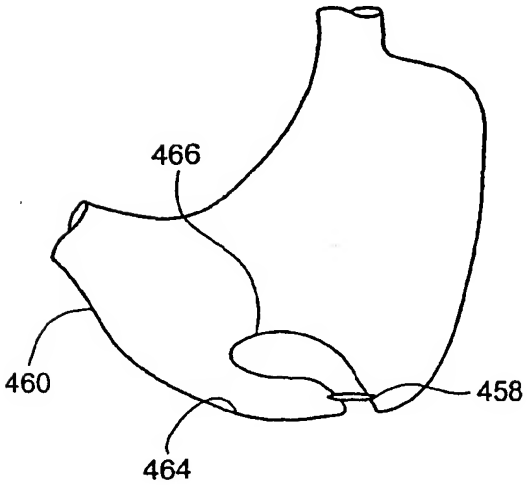

FIG. 27C

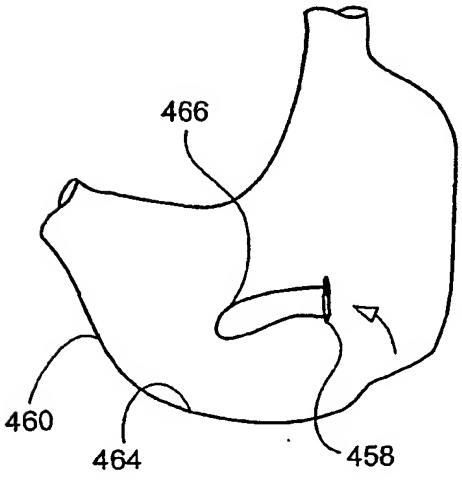

FIG. 27D

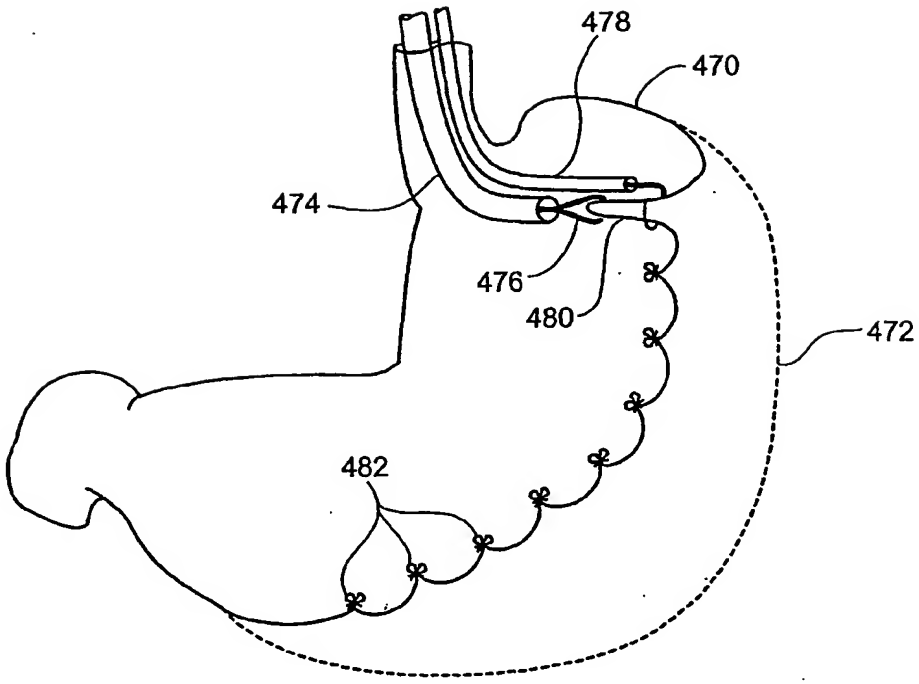

FIG. 28

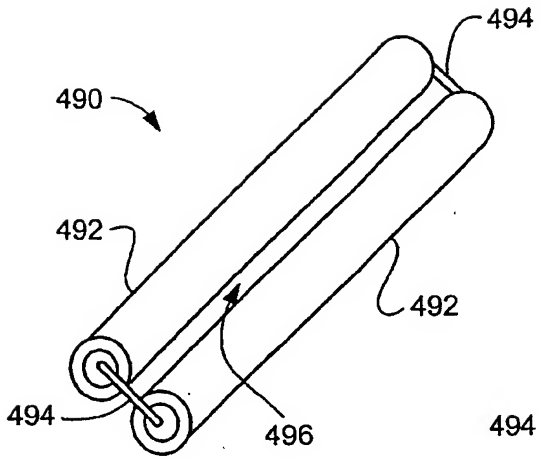

FIG. 29A

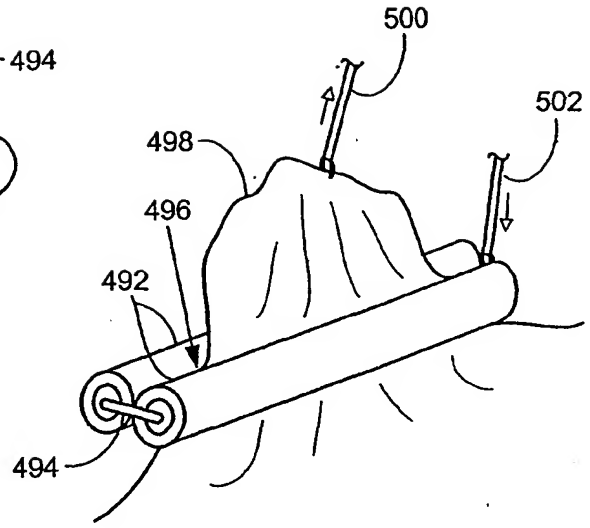

FIG. 29B

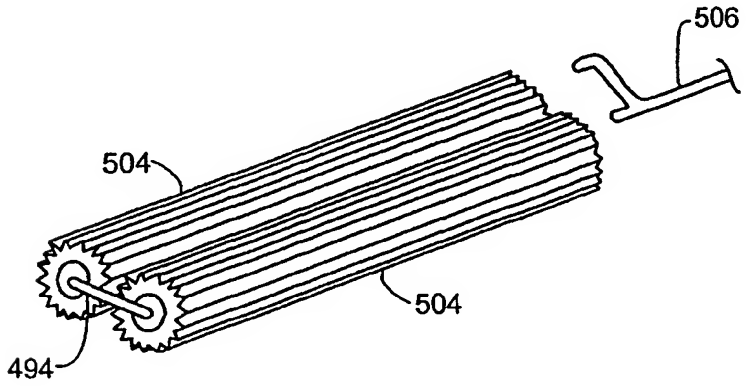

FIG. 29C

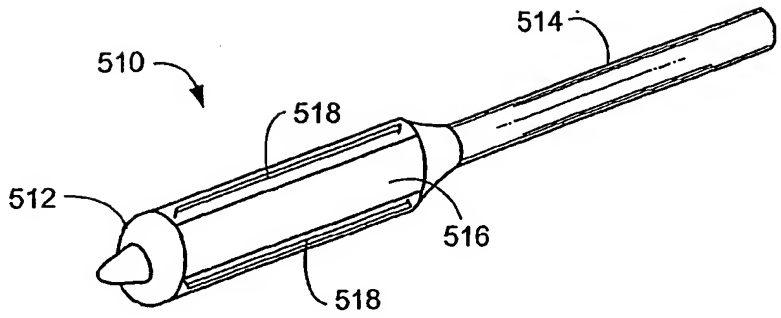

FIG. 30

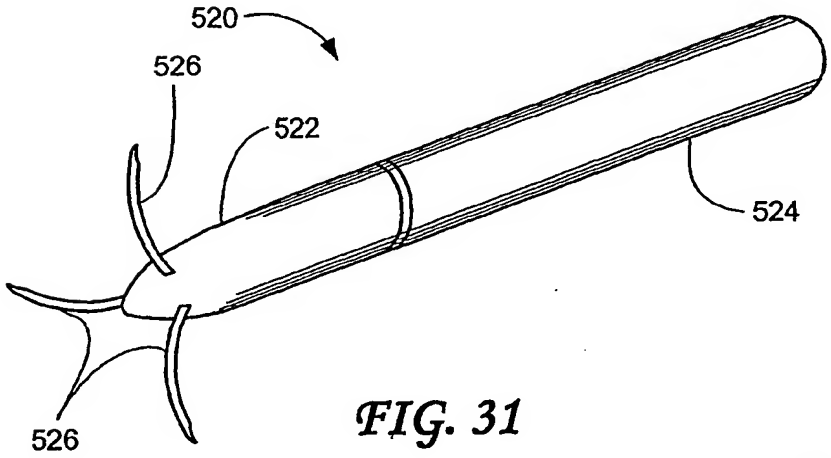

FIG. 31

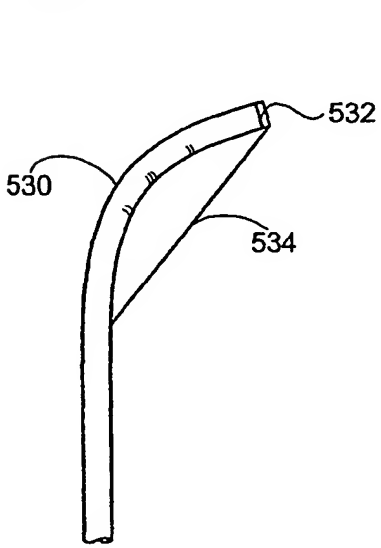

FIG. 32A

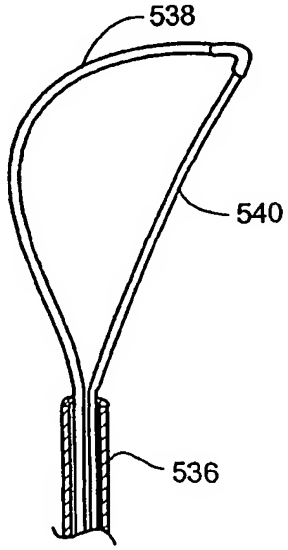

FIG. 32B

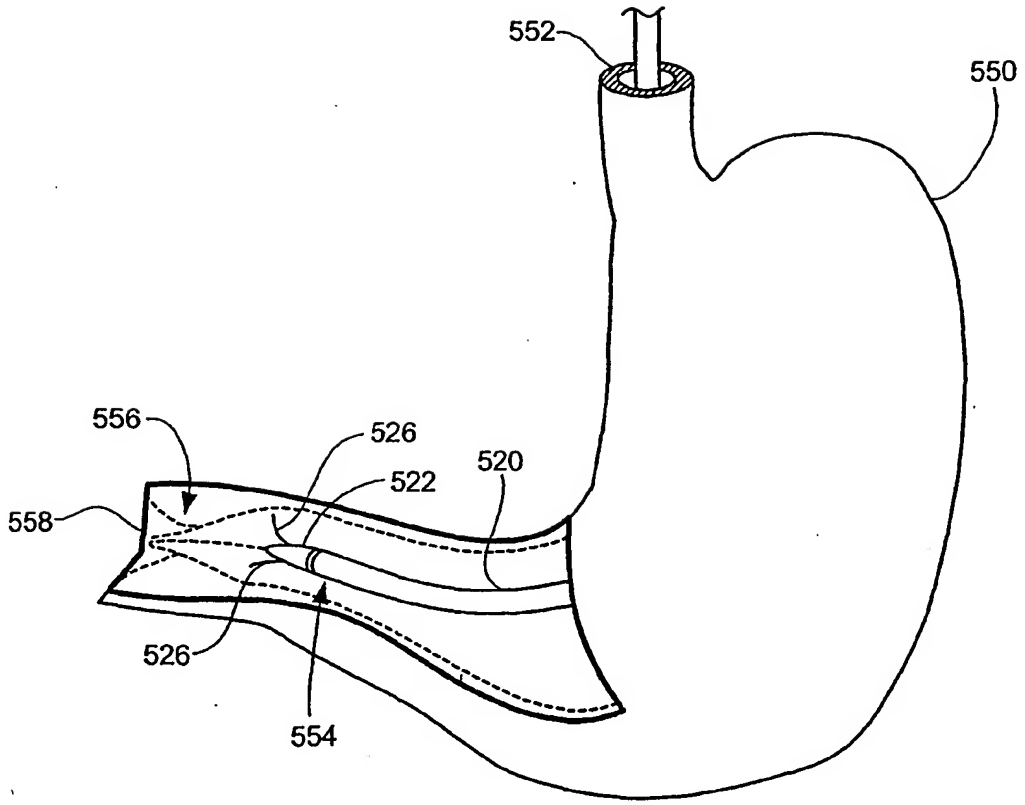

FIG. 33

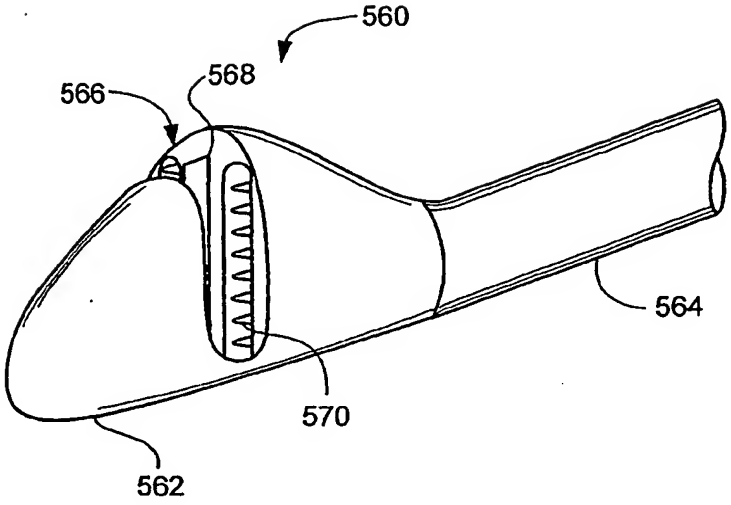

FIG. 34A

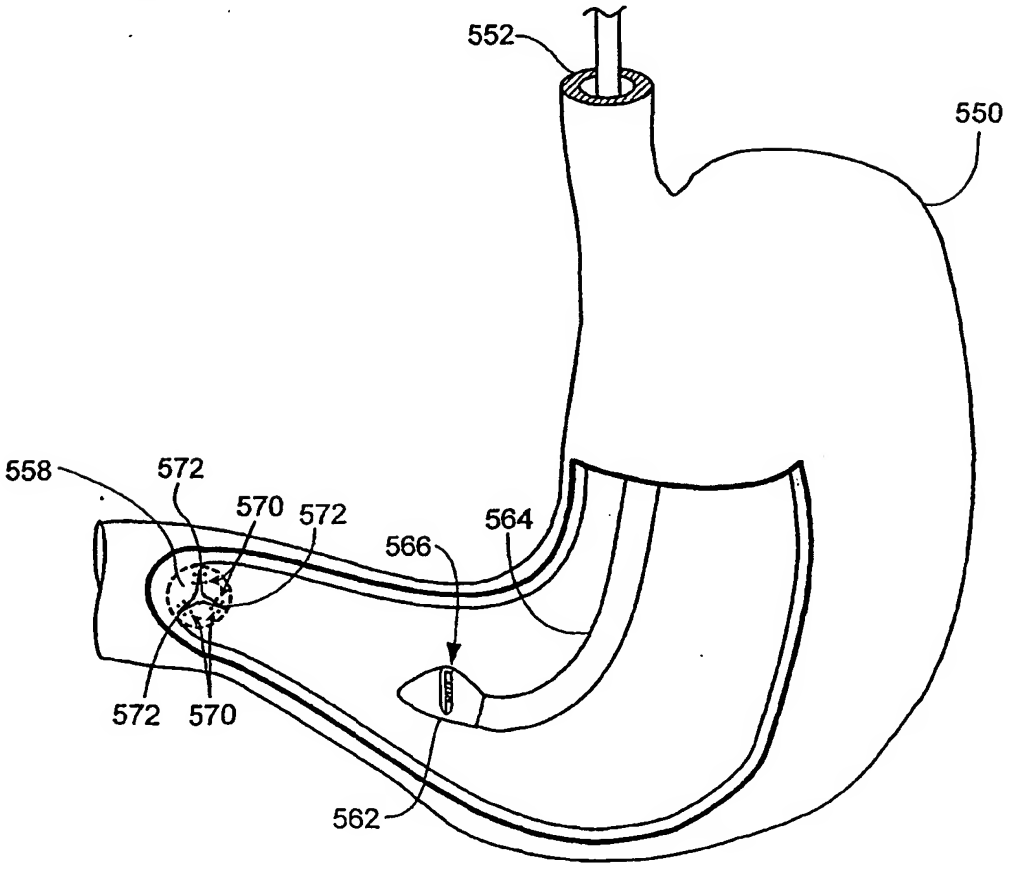

FIG. 34B

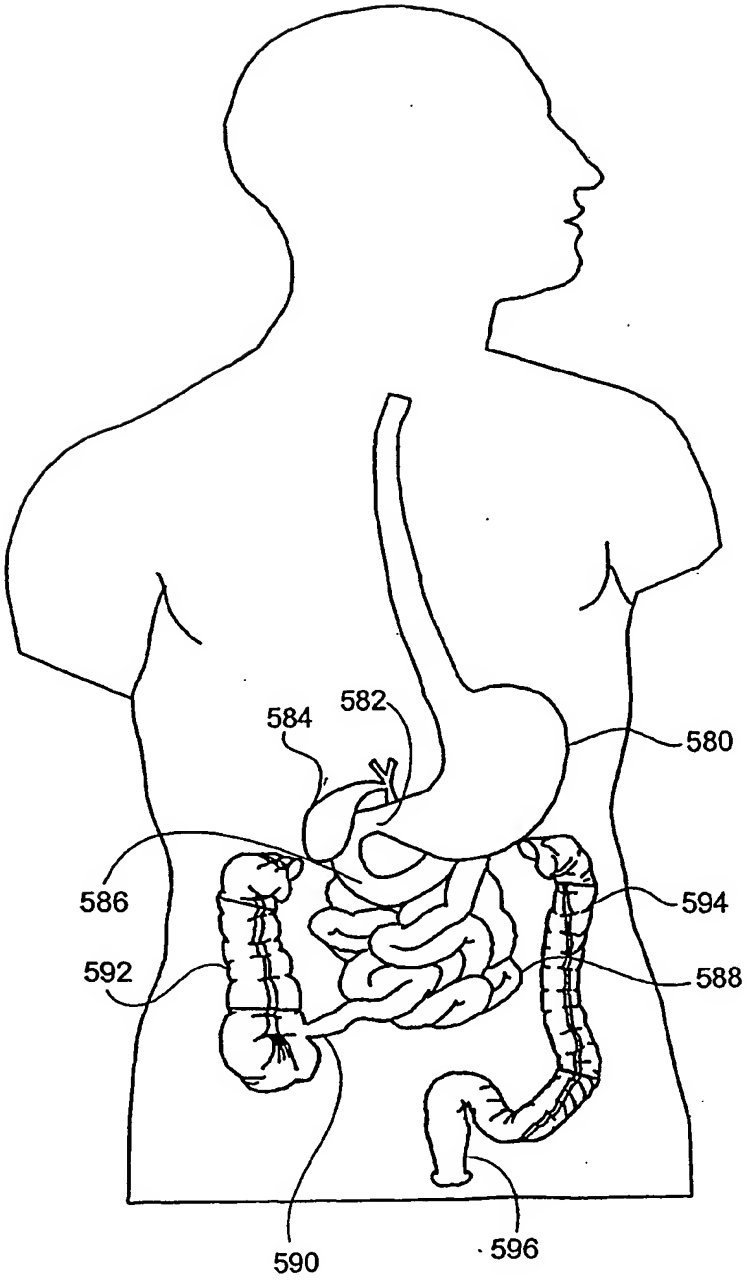

FIG. 35

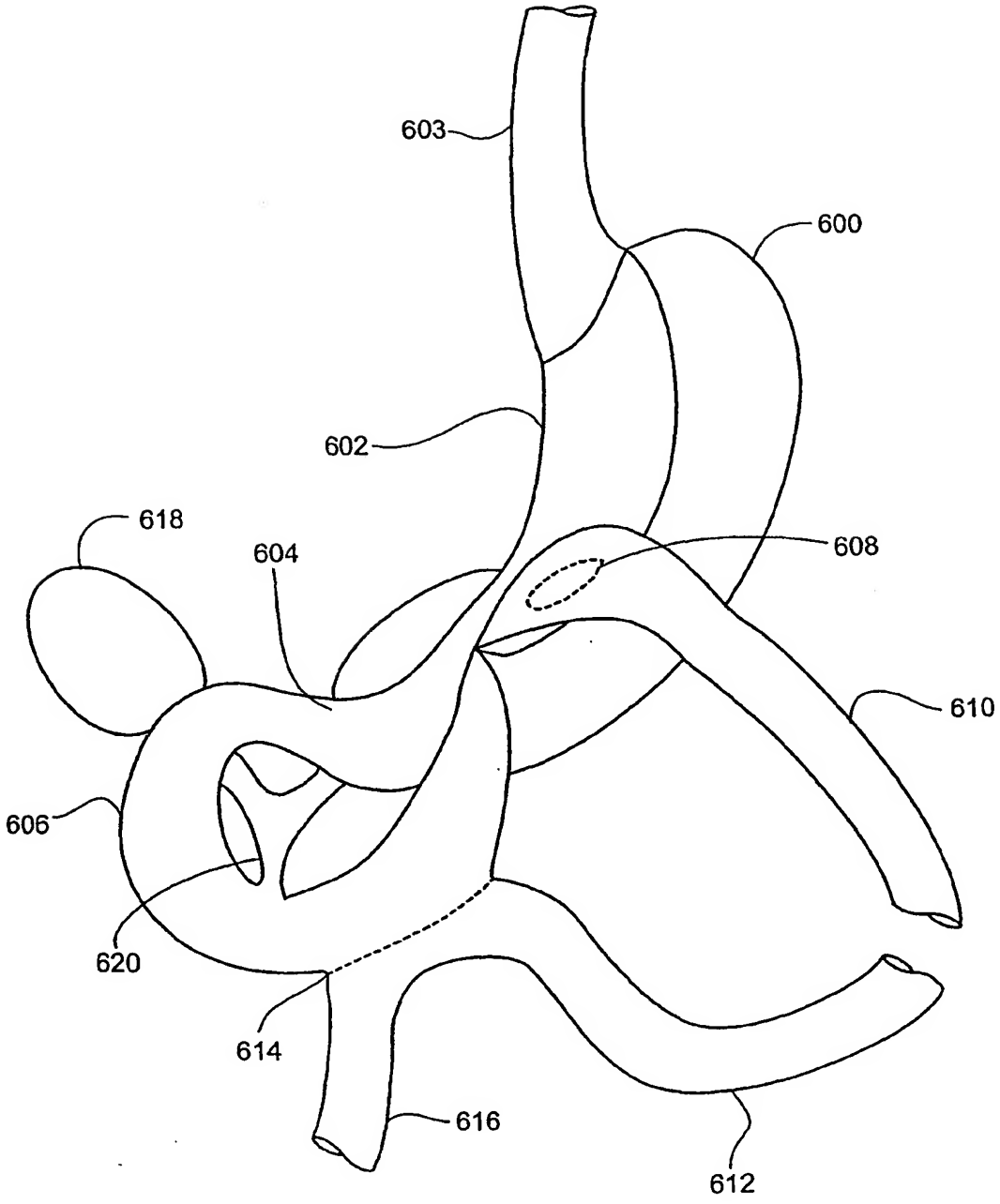

FIG. 36

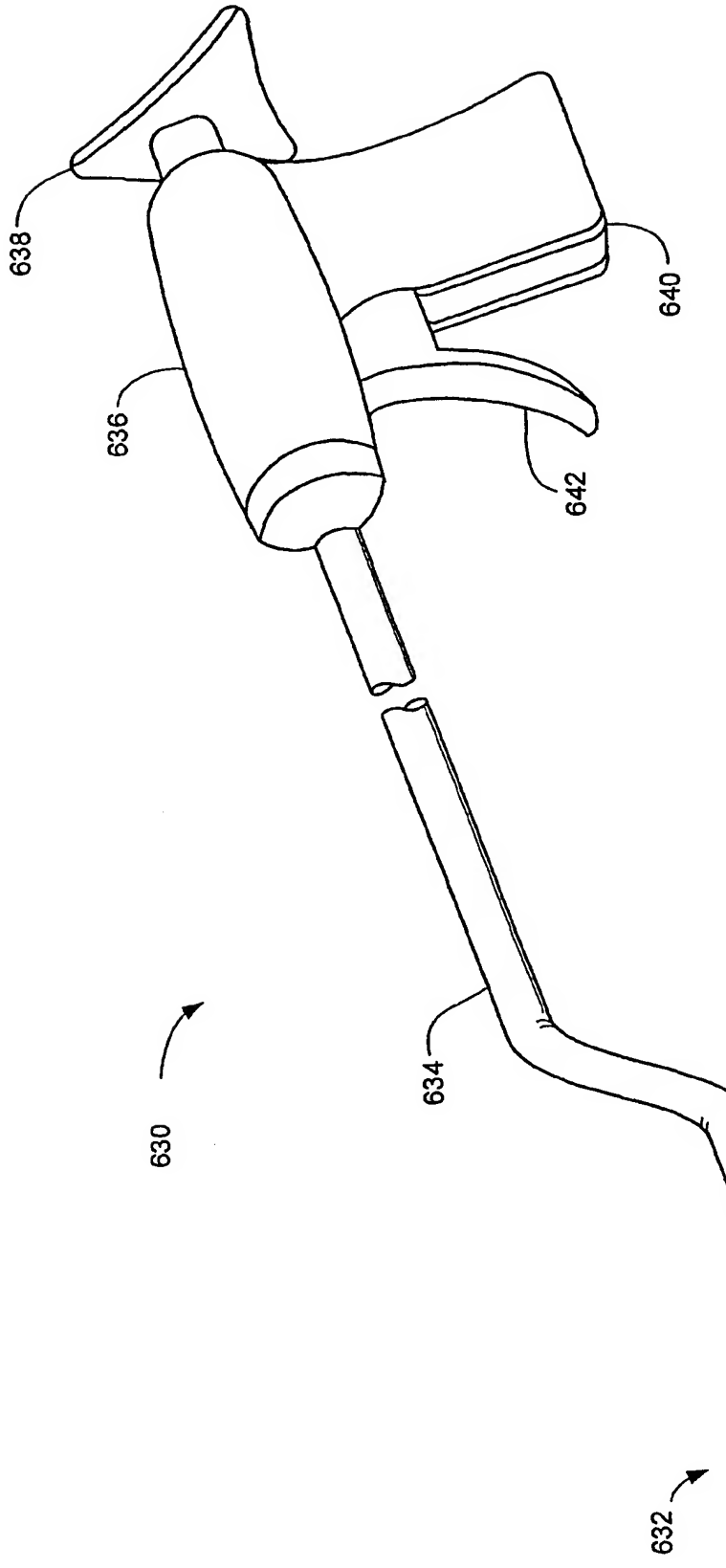

FIG. 37

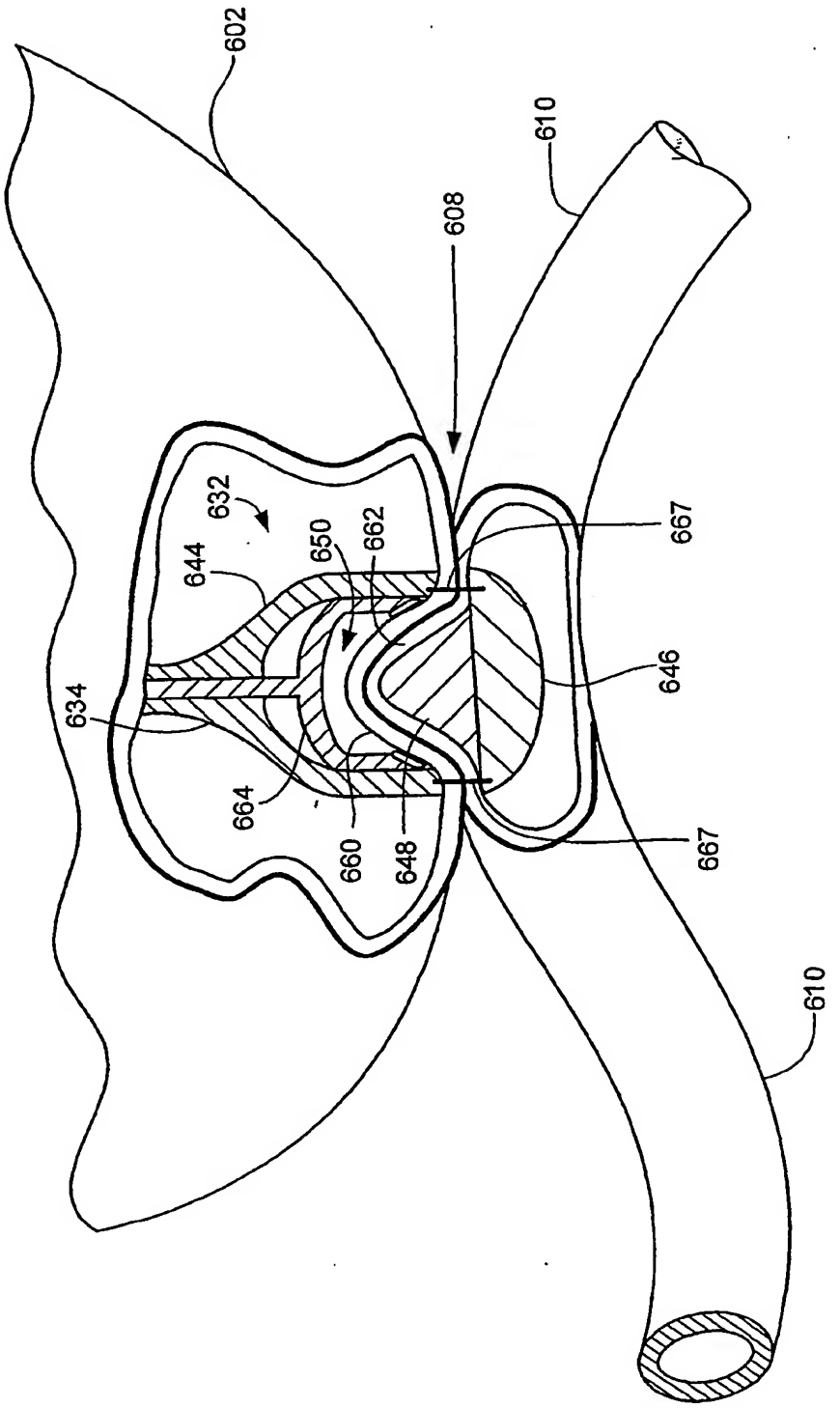

FIG. 38

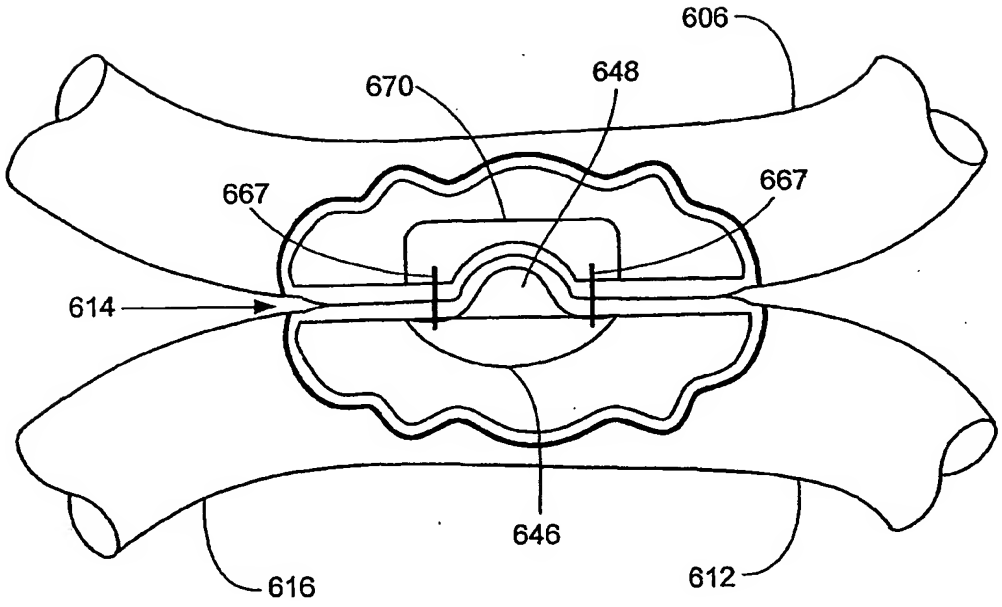

FIG. 39

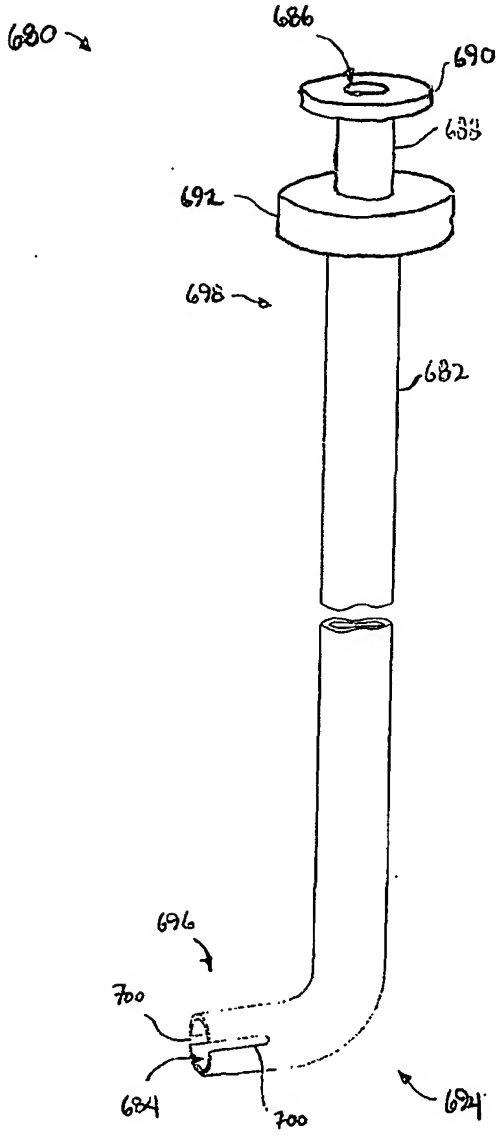

FIG. 40A

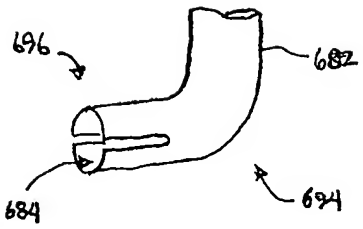

FIG 40B

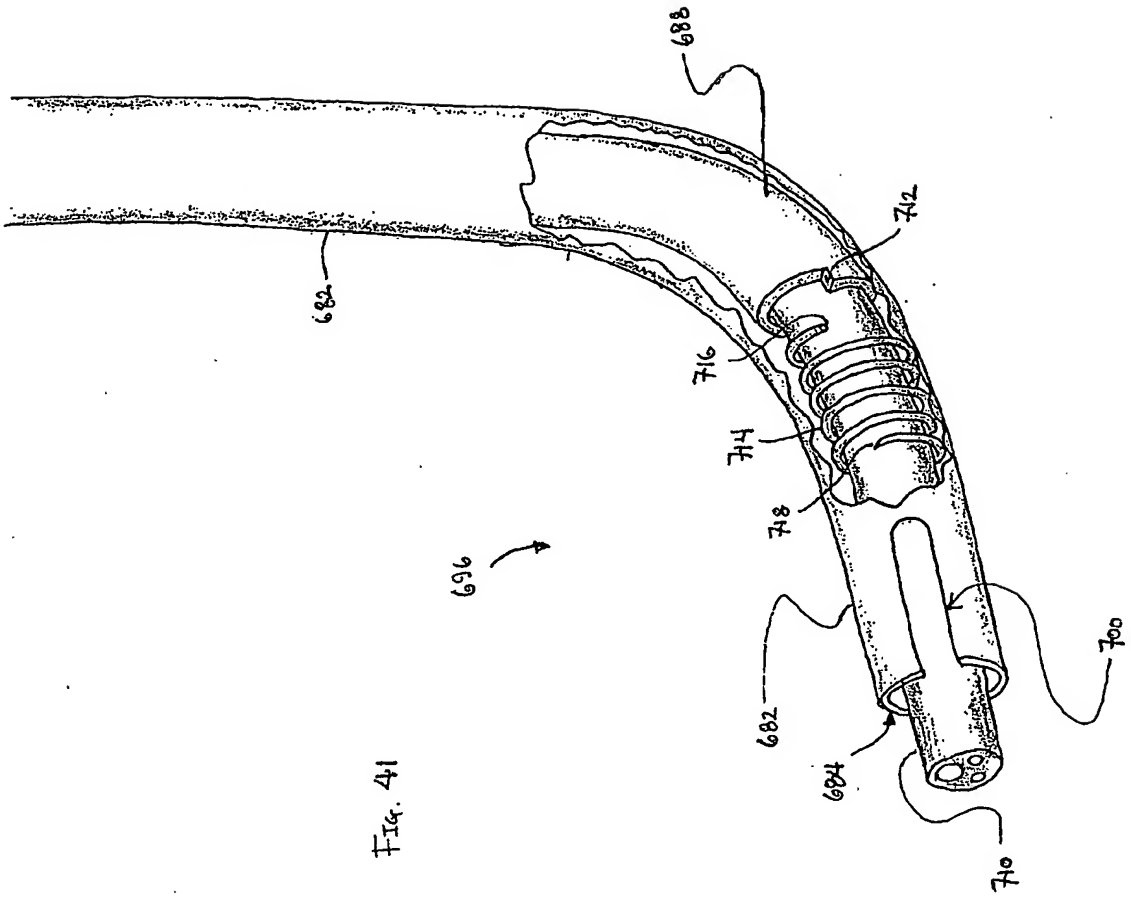

Fig. 41

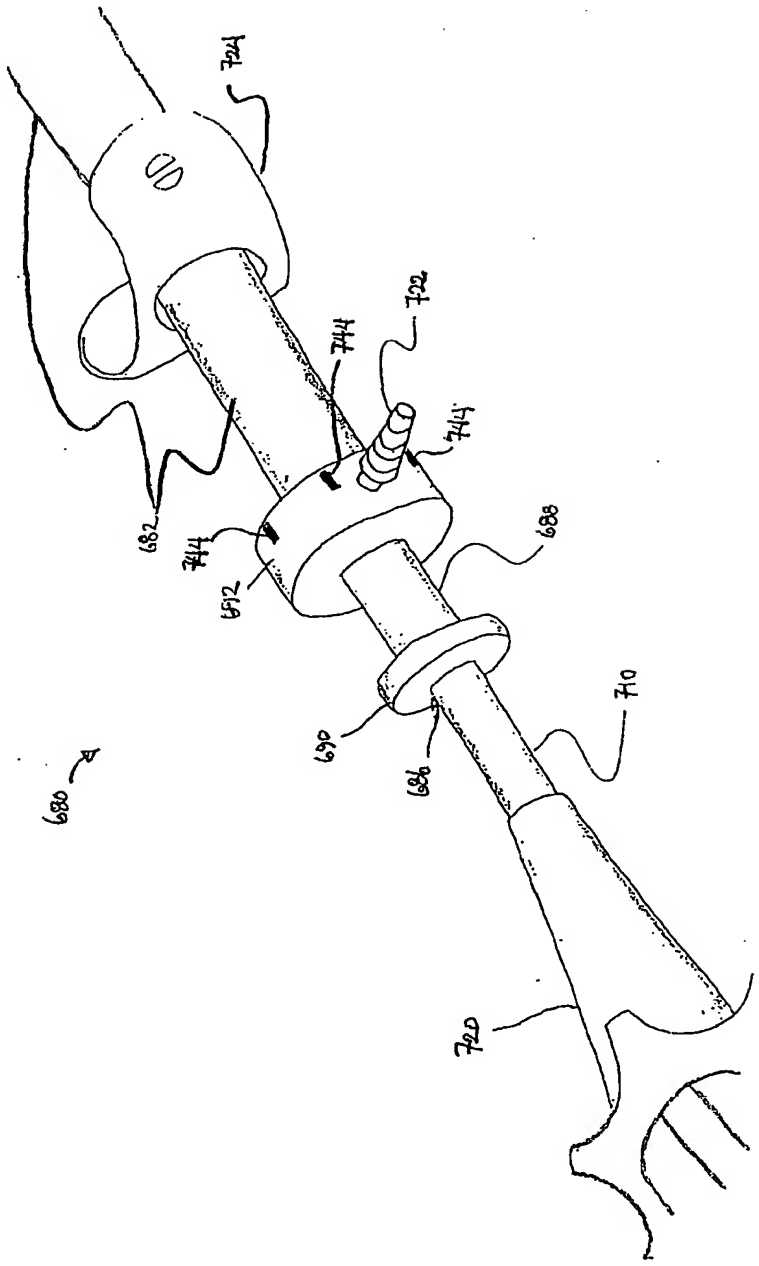

FIG. 42A

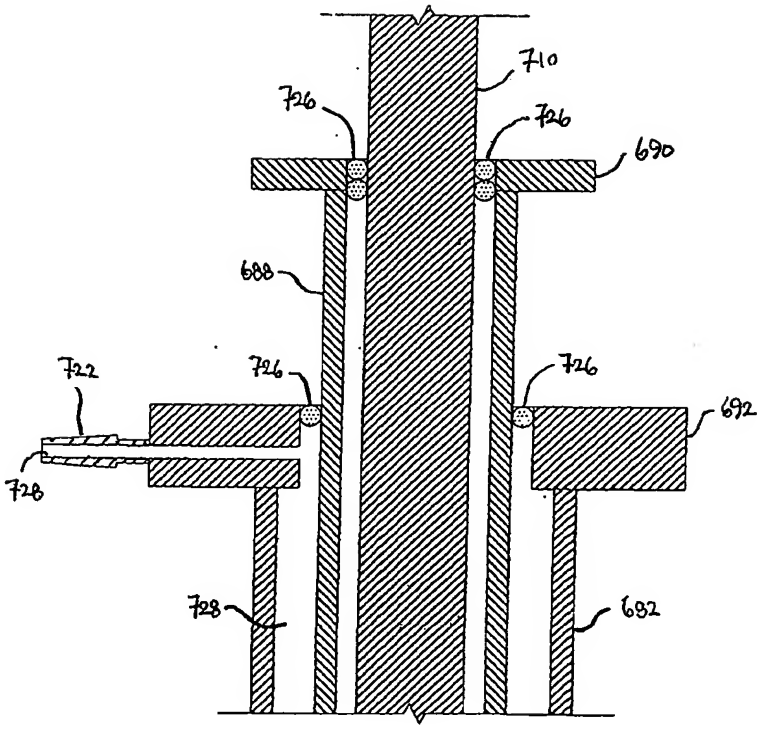

FIG. 42B

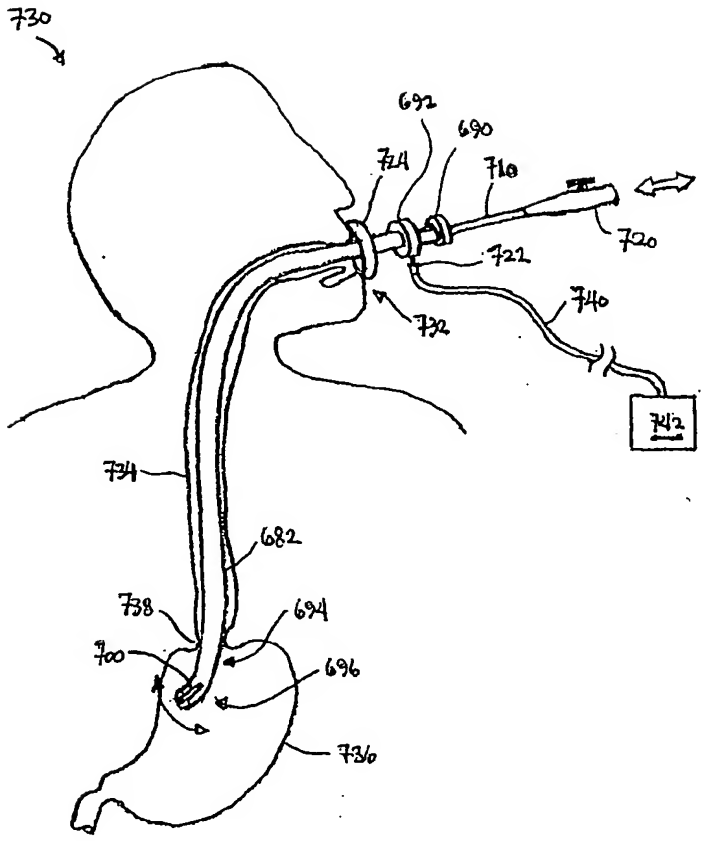
730
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Fig. 43

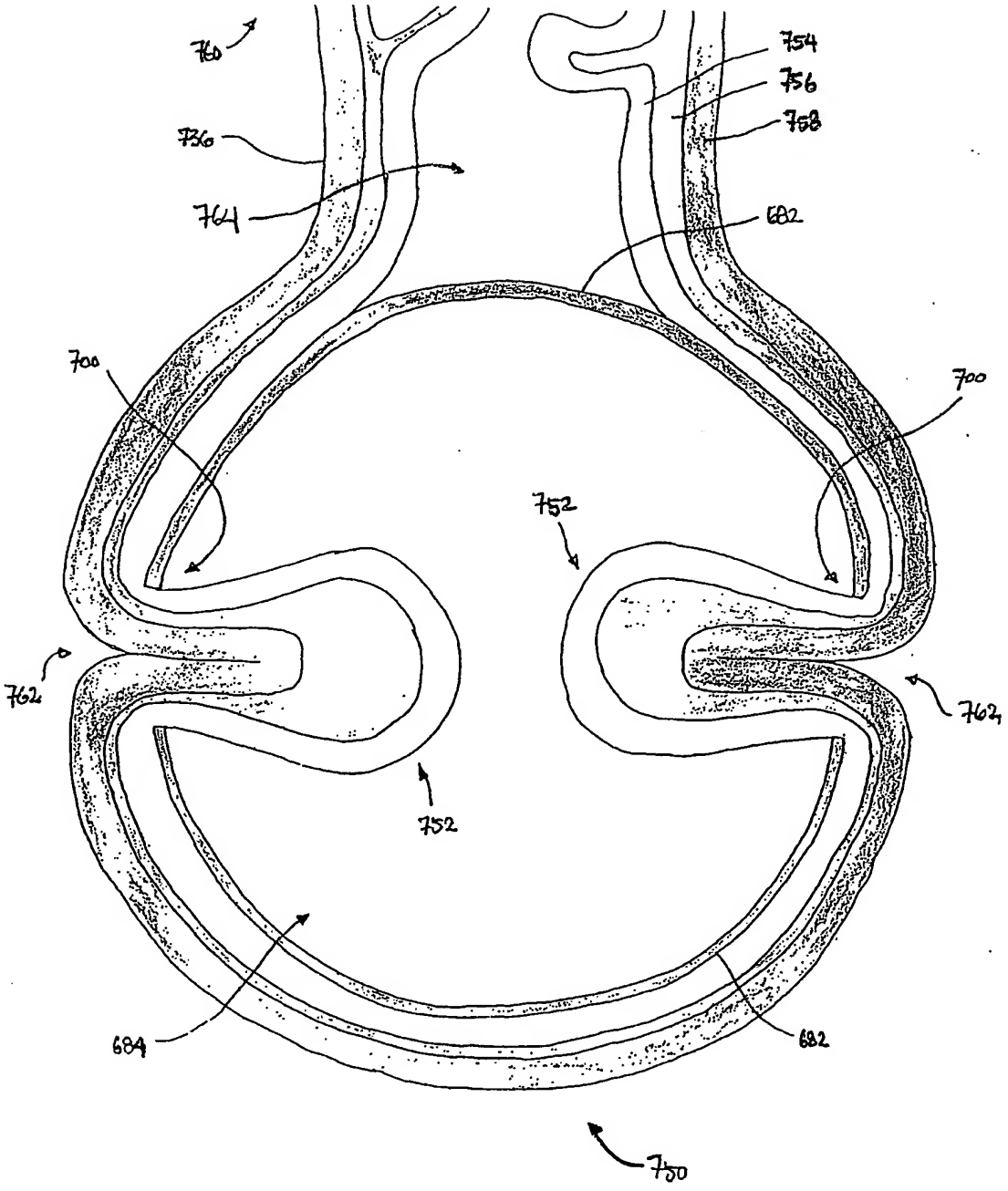


FIG. 44

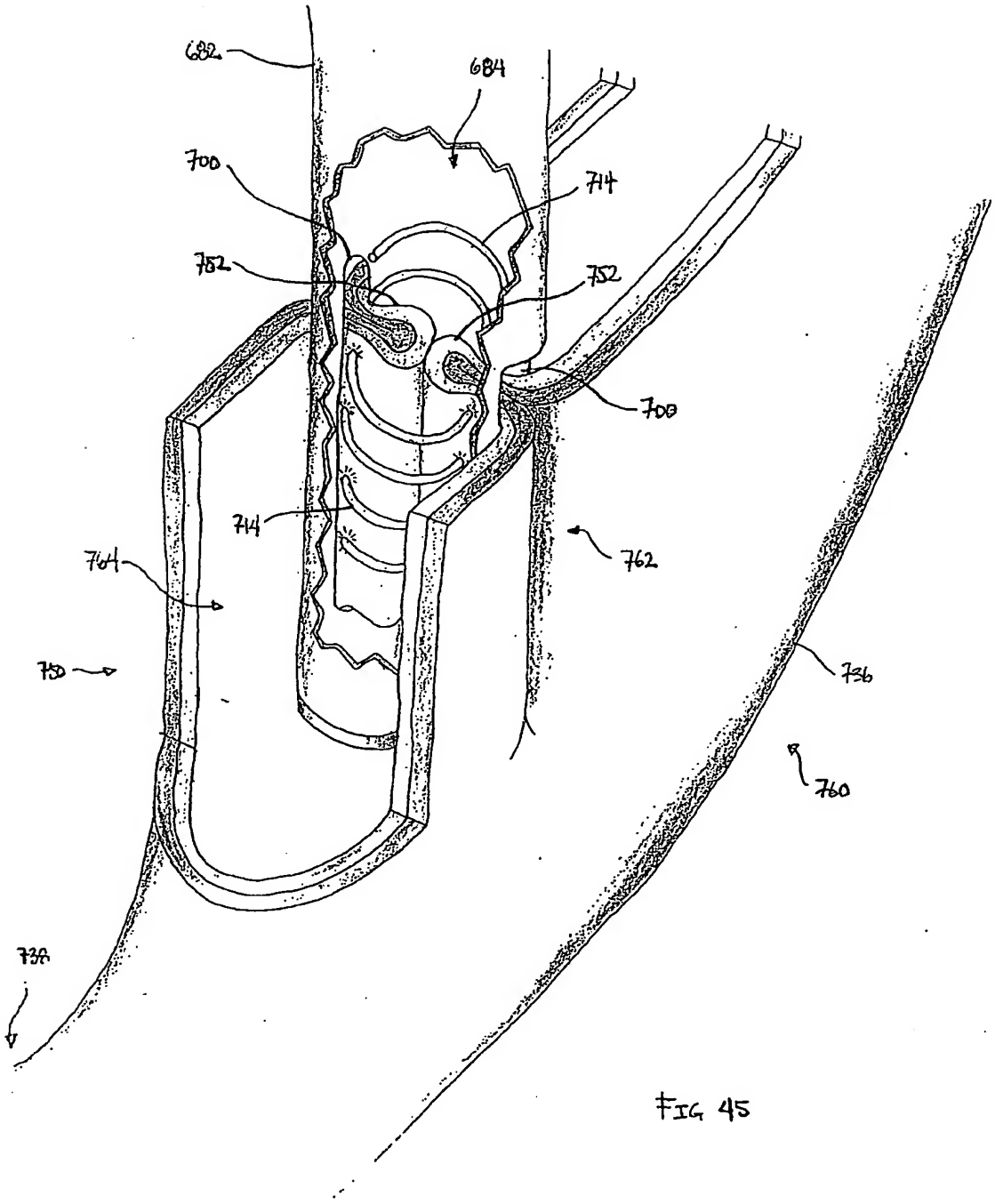


FIG 45

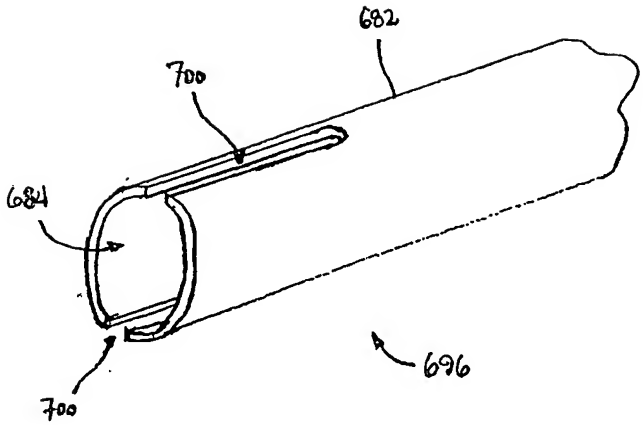


FIG. 46A

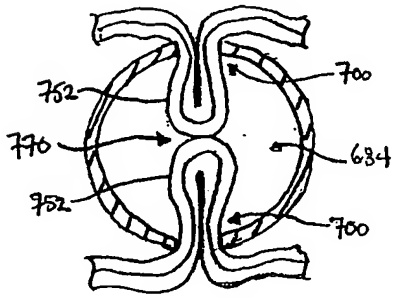


FIG. 46B

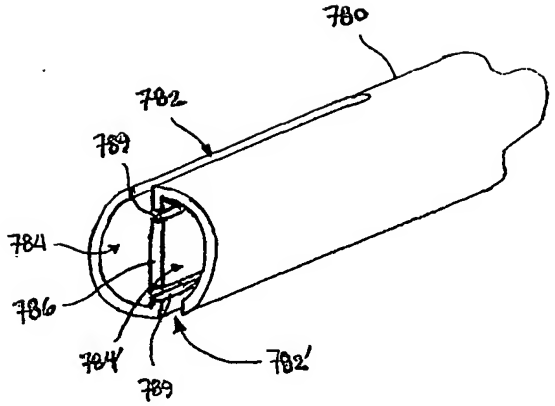


FIG. 47A

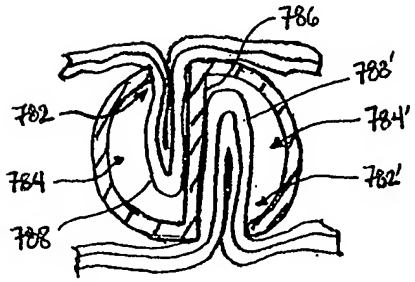
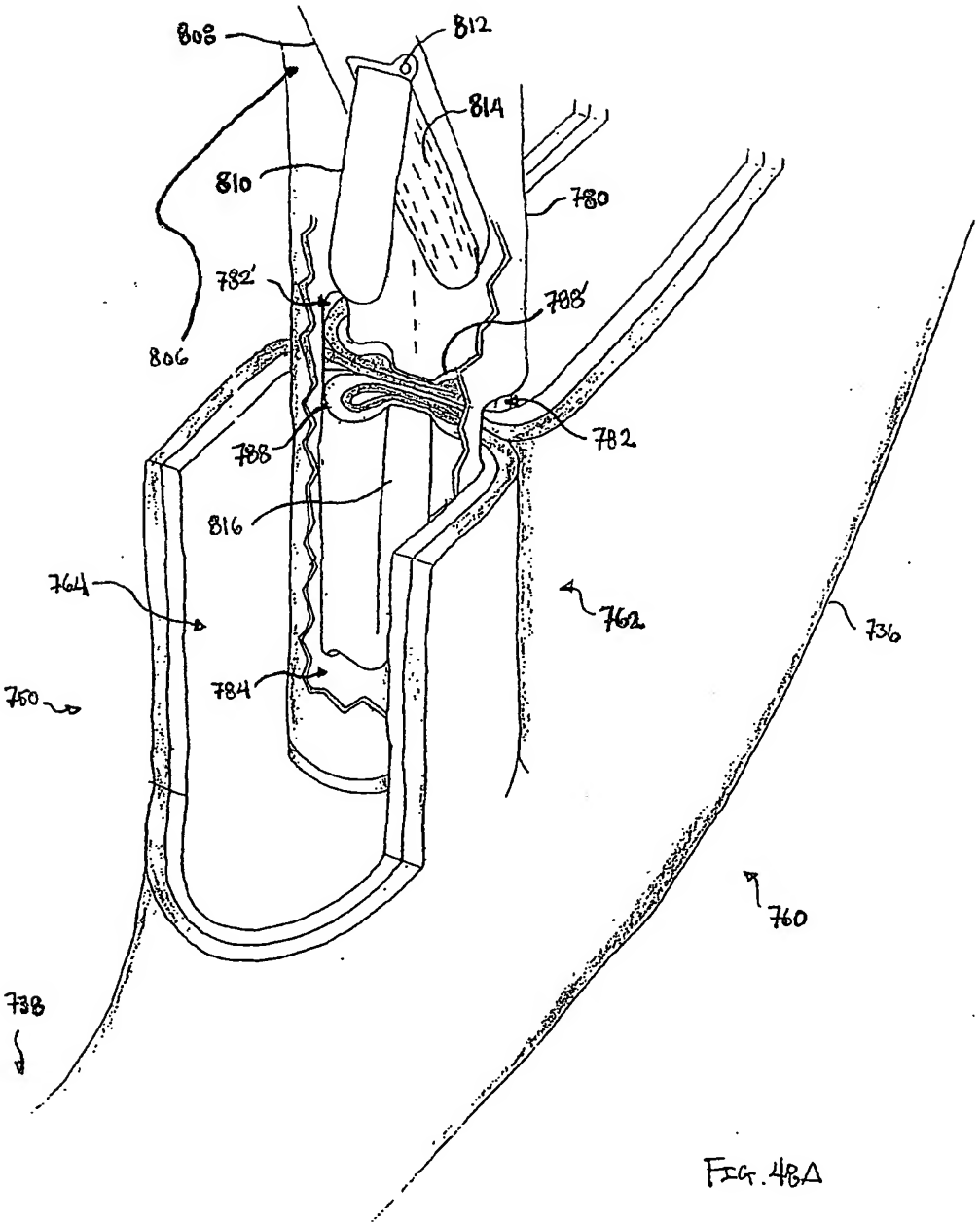


FIG. 47B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782'
708'
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750
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FIG. 48A

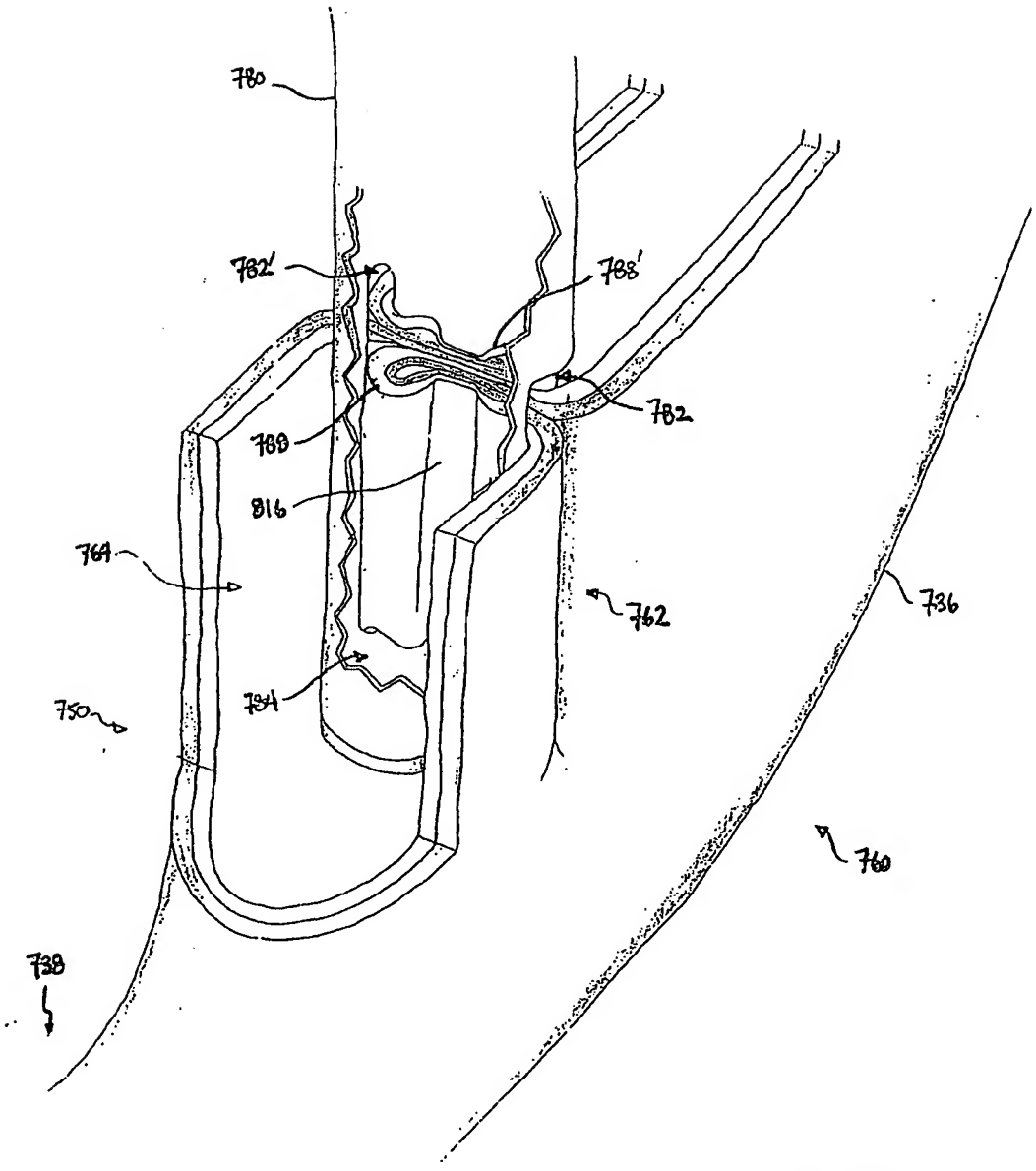


FIG. 48B

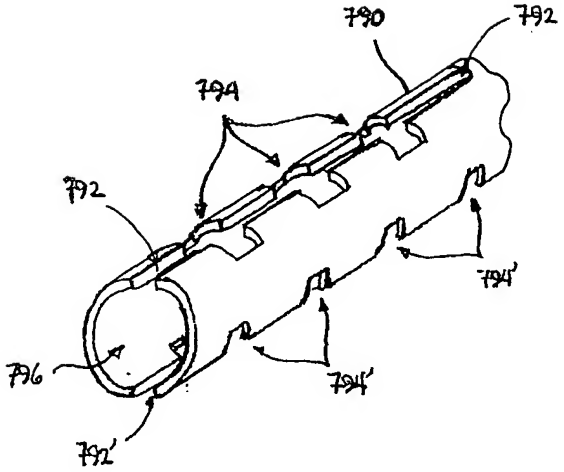


FIG. 49A

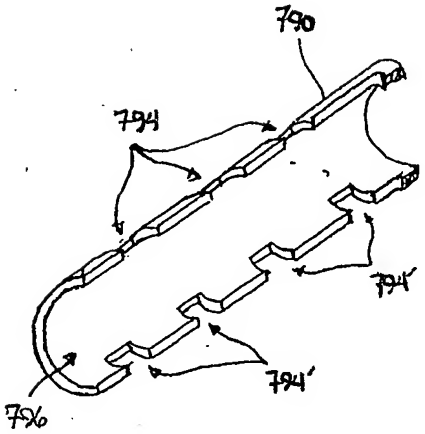


FIG. 49B

FIG. 50A

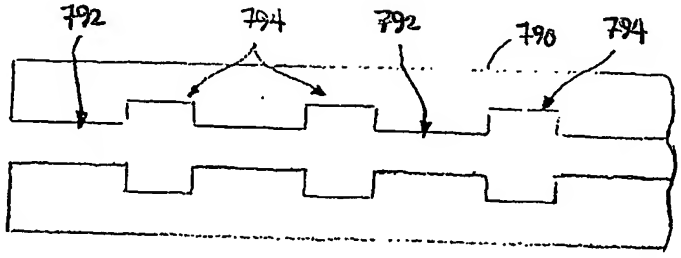
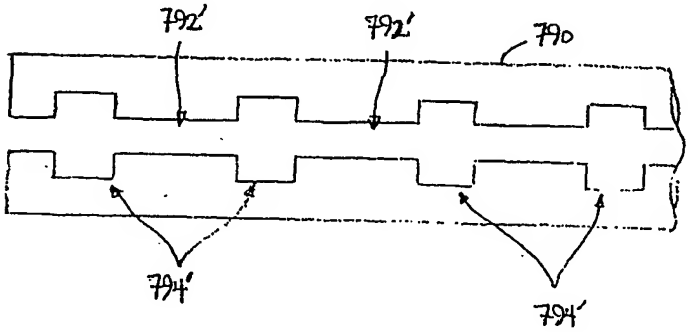


FIG 50B



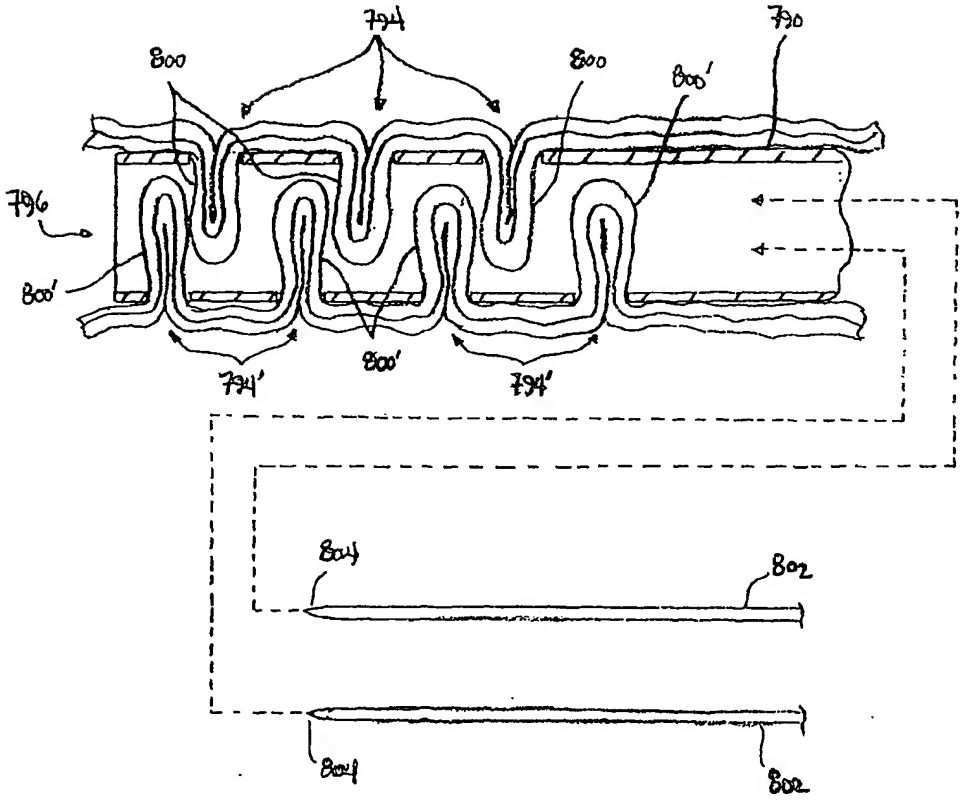


FIG. 51

PATENT COOPERATION TREATY

PCT

REC'D 17 SEP 2002
WIPO PCT

DECLARATION OF NON-ESTABLISHMENT OF INTERNATIONAL SEARCH REPORT

(PCT Article 17(2)(a), Rules 13ter.1(c) and Rule 39)

Applicant's or agent's file reference	IMPORTANT DECLARATION	Date of mailing *(day/month/year)*
514362000240		16/09/2002
International application No.	International filing date *(day/month/year)*	(Earliest) Priority date *(day/month/year)*
PCT/US 02/17077	29/05/2002	30/05/2001
International Patent Classification (IPC) or both national classification and IPC	A61F5/00,A61B17/064,A61B19/00	
Applicant		
SATIETY, INC.		

This International Searching Authority hereby declares, according to Article 17(2)(a), that **no international search report will be established** on the international application for the reasons indicated below

1. [X] The subject matter of the international application relates to:
   - a. [ ] scientific theories.
   - b. [ ] mathematical theories
   - c. [ ] plant varieties.
   - d. [ ] animal varieties.
   - e. [ ] essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes.
   - f. [ ] schemes, rules or methods of doing business.
   - g. [ ] schemes, rules or methods of performing purely mental acts.
   - h. [ ] schemes, rules or methods of playing games.
   - i. [X] methods for treatment of the human body by surgery or therapy.
   - j. [X] methods for treatment of the animal body by surgery or therapy.
   - k. [ ] diagnostic methods practised on the human or animal body.
   - l. [ ] mere presentations of information.
   - m. [ ] computer programs for which this International Searching Authority is not equipped to search prior art.

2. [ ] The failure of the following parts of the international application to comply with prescribed requirements prevents a meaningful search from being carried out:
   [ ] the description [ ] the claims [ ] the drawings

3. [ ] The failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions prevents a meaningful search from being carried out:
   - [ ] the written form has not been furnished or does not comply with the standard.
   - [ ] the computer readable form has not been furnished or does not comply with the standard.

4. Further comments: SEE ADD.SHEET

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Alicja Van der Heijden

Form PCT/ISA/203 (July 1998)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 203

A meaningful search is not possible on the basis of all claims for the following reasons.

Claims 1-10,30-41,75-95,121-135,201-224,265-281 are directed to methods for treatment of the human or animal body by surgery and are therefore excluded under Rule 39.1(iv) PCT.

The present application contains 182 claims not excluded under Rule 39.1(iv). These include 11 claims presented as independent claims differing from one another by their technical content and/or in the wording used to define such technical content, and including within their scope an extremely large number of possible devices.

The large number and also the wording of the claims presently on file renders it difficult if not impossible to determine the matter for which protection is sought. As a result the present application fails to comply with the requirement, see Article 6 PCT, of clarity and conciseness, see also Rule 6.1(a) PCT, to the extent that a meaningful search is impossible. Consequently no search report can be established for the present application.

Although no formal objection concerning lack of unity has been made at this stage because of the above objection under Article 6 PCT, it would appear that several of the independent claims define inventions not linked by a single inventive concept, see Rule 13 PCT.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.